

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

APPLE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 22-1378-MN-JLH
)	
MASIMO CORPORATION and)	JURY TRIAL DEMANDED
SOUND UNITED, LLC,)	
)	
Defendants.)	
<hr style="width: 45%; margin-left: 0;"/>		
MASIMO CORPORATION and)	
CERCACOR LABORATORIES, INC.,)	
)	
Counter-Claimants,)	
)	
v.)	
)	
APPLE INC.,)	
)	
Counter-Defendant.)	

NOTICE OF SUBPOENA

PLEASE TAKE NOTICE that, pursuant to Rule 45 of the Federal Rules of Civil Procedure, Plaintiff/Counter-Defendant Apple Inc., will serve the attached subpoena (Exhibit 1) in the above referenced action.

VIA ELECTRONIC MAIL

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EXHIBIT 1

UNITED STATES DISTRICT COURT

for the
District of Delaware

Apple Inc.

Plaintiff

v.

Masimo Corporation and Sound United, LLC

Defendant

Civil Action No. 22-cv-1378-MN-JLH

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To:

Itamar Medical, Inc.

c/o Roe Arielly Blumberger, 3290 Cumberland Club Dr., Suite 100, Atlanta, GA 30339

(Name of person to whom this subpoena is directed)

☒ **Testimony:** YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters:

SEE ATTACHMENT A

Place: TransPerfect Translations 1170 Peachtree St. N.E. Atlanta, GA 30309	Date and Time: 09/08/2023 10:00 am
--	---------------------------------------

The deposition will be recorded by this method: Stenographically, audiotaped, and videotaped

☒ **Production:** You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

See Schedule A (attached). Documents to be produced on or before August 25, 2023, to:
Jamie Kringstein, Desmarais LLP, 230 Park Avenue, New York, NY 10169
jkringstein@desmaraisllp.com

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 08/10/2023

CLERK OF COURT

OR

/s/ Jamie L. Kringstein

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Plaintiff Apple Inc.

, who issues or requests this subpoena, are:
Jamie Kringstein | Desmarais LLP | 230 Park Ave., New York, NY 10169 | 212-808-2921 | jkringstein@desmaraisllp.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 22-cv-1378-MN-JLH

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____
on *(date)* _____ .

☐ I served the subpoena by delivering a copy to the named individual as follows: _____

_____ on *(date)* _____ ; or

☐ I returned the subpoena unexecuted because: _____
_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also
tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of
\$ _____ .

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)**(c) Place of Compliance.**

(1) For a Trial, Hearing, or Deposition. A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

- (A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- (B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
 - (i) is a party or a party's officer; or
 - (ii) is commanded to attend a trial and would not incur substantial expense.

(2) For Other Discovery. A subpoena may command:

- (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
- (B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) Avoiding Undue Burden or Expense; Sanctions. A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) Command to Produce Materials or Permit Inspection.

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

- (i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
- (ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) Quashing or Modifying a Subpoena.

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

- (i) fails to allow a reasonable time to comply;
- (ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
- (iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
- (iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

- (i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
- (ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) Producing Documents or Electronically Stored Information. These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) Claiming Privilege or Protection.

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

- (i) expressly make the claim; and
- (ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

ATTACHMENT A

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

1. As used herein, the terms “Zoll,” “You,” or “Your” means Zoll Medical Corporation, Itamar Medical Inc., Itamar Medical Ltd., and all of their predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

2. As used herein, “Apple” means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

3. As used herein, “Masimo” means Masimo Corporation, Cercacor Laboratories, Inc., and all their predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all of their officers, directors, principals, agents, employees, independent contractors working under their control, attorneys, and other persons acting on their behalf.

4. As used herein, “Masimo Asserted Patents” means U.S. Patent No. 10,687,743 (“the ’743 Patent”), U.S. Patent No. 10,722,159 (“the ’159 Patent”), U.S. Patent No. 8,190,223 (“the ’223 Patent”), U.S. Patent No. 10,736,507 (“the ’507 Patent”), and U.S. Patent No. 10,984,911 (“the ’911 Patent”).

5. As used herein, “Relevant Date” means September 20, 2012.

6. As used herein, “Exhibits” means Exhibits 1-4 attached hereto.

7. As used herein, “Blood Oxygen and Heart Rate Features” means the product feature(s) relating to monitoring, measuring, sensing, detecting, and/or obtaining blood oxygen (SpO2) and/or heart rate measurements, including all hardware, software, firmware, components, modules, applications, and devices involved in such features, that were made or sold before the Relevant Date.

8. As used herein, “Product” means any machine, manufacture, apparatus, device, system, process, service, method, or instrumentality which is designed to function together electrically, mechanically, chemically, or otherwise, to achieve a particular function or purpose, including those offered for sale, sold, imported, or under development.

9. As used herein, “Relevant Products” means (1) Itamar Medical Watch-PAT100, Watch-PAT200, Endo-PAT2000 and similar products, (2) Itamar Medical zzzPAT and any similar software (3) the products described in Exhibits 1-4, (4) any Product made or sold by or for You having Blood Oxygen and Heart Rate Features before the Relevant Date, and (5) any related Products or modules having Blood Oxygen and Heart Rate Features before the Relevant Date.

10. As used herein, “Source Code” means any human-readable programming language or format that defines software, firmware or integrated circuits, including but not limited to, computer code, scripts, assembly, binaries, object code, Register Transfer Level (“RTL”) descriptions, VHDL, Verilog, and other Hardware Description Language (“HDL”) formats.

11. The term “Third Party” means any person or entity other than You, Masimo, or Apple.

12. As used herein, the term “document” shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer

to any electronically stored information (“ESI”) or any tangible object or thing that contains, conveys, or records information.

13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

14. As used herein, “person” means any natural person or any business, legal, or governmental entity or association.

15. As used herein, “include” and “including” shall be construed to mean “without limitation,” so as to give the broadest possible meaning to interrogatories and definitions containing those words.

16. As used herein, “and” and “or” shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.

17. As used herein, “any” and “all” shall each be construed to mean “each and every,” so as to acquire the broadest meaning possible.

18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

19. As used herein, “related” or “relating” to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

20. As used herein, “identify” as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document’s title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the

document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.

21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available to You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.

2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.

3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.

4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

REQUESTS FOR PRODUCTION

1. Documents sufficient to identify and describe the functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products and all components, modules, applications, hardware, software, and firmware contained therein, including, without limitation, user manuals, brochures, presentations, user guides, product literature, engineering specifications, circuit diagrams, architectural diagrams, bills of materials, technical manuals, product specifications, data sheets, laboratory notebooks, research papers, test data and results, analyses, invention disclosure forms, reports, service manuals, operator's manuals, implementation guides, white papers, product tutorials, and non-public documentation.

2. Documents sufficient to identify and describe the conception, design, research, development, testing, use, operation, maintenance, marketing, modifying, sale, offer for sale, and supply of the Relevant Products, including the persons and entities involved.

3. Documents, communications, and things comparing the Apple Watch to the Relevant Products.

4. Other versions of the Exhibits and documentation related to the Exhibits.

5. Documents sufficient to show the earliest dates that each of the Relevant Products were first conceived; reduced to practice; and made, sold, used (including by third parties such as end users), offered for sale, in public use, and otherwise available to the public in the United States, including but not limited to documents relating to any conference, seminar, exhibition, convention, or trade show at which such Product is or was discussed, referred to, advertised, displayed, demonstrated, or shown, such as, without limitation, product specifications, catalogs, announcements, advertisements, brochures, articles, pamphlets, price lists, invoices, purchase orders, sales records, or other promotional, marketing, or sales materials.

6. Publications related to the Relevant Products that were made available to the public.

7. Three samples of each Relevant Product.
8. Source Code sufficient to show the functionality of the Blood Oxygen and Heart Rate Features of the Relevant Products.
9. Documents sufficient to show the authorship and authenticity of all the documents produced in response to this subpoena.

DEPOSITION TOPICS

1. The functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products.

2. The earliest dates that each Relevant Product was reduced to practice, made, sold, offered for sale, in public use, or otherwise available to the public.

3. The subject matter contained within the documents produced in response to Requests For Production herein, including the authentication thereof.

4. The authorship and authenticity of the documents produced in response to the Requests For Production herein.

EXHIBIT 1



Endo-PAT2000


User Manual

Itamar Medical REF OM1695012



This product and/or method of use, is covered by one or more of the following US patents: 6319205, 6322515, 6461305, 6488633, 6916289, 6939304, 7374540, as well as any pending US patent applications and corresponding patents and/or applications filed in other countries.

Itamar Medical Ltd.

This manual and the information contained herein are confidential and are the sole property of  Itamar Medical Ltd. Only Itamar Medical Ltd. or its licensees have the right to use this information. Any unauthorized use, disclosure or reproduction is a direct violation of Itamar Medical's proprietary rights.

THE USE OF THE ENDO-PAT2000 SYSTEM IS GOVERNED BY A LICENSE AGREEMENT. ANY USE OTHER THAN THAT DESCRIBED IN SUCH LICENSE AGREEMENT IS PROHIBITED.

DISCLAIMER

Itamar Medical Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this device other than that which adheres to the instructions and safety precautions contained herein and in all supplements hereto and according to the terms of the warranty provided in Appendix A.

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ISO 9001:2008 and ISO 13485:2003

See appendix B for contact information of the regulatory authorized representative

Itamar Medical Ltd.

Record of Revisions

Revision: 14

Revision	Date	Description	Chapter	Pages
0	Jul 02	Preliminary	All	All
1	Oct 02	Base	All	All
2	May 03	Update	All	All
3	August 03	Update	All	All
4	September 03	Update	All	All
5	November 03	Update	All	All
6	May 04	Update following FDA clearance	All	All
7	December 04	Update	All	All
8	May 05	Update Appendix A	All	54
9	January 07	General update for new S/W version, arm supports and general overhaul of the manual	All	All
10	May, 07	General update for new S/W version, new USB to COM driver	All	All
11	June 08	Updating ISO logo, list of standards, Medes address. Adding of AI note.	All	i, 4, 5,74,77
12	Jan 09	Updating Itamar Medical address.	All	i, 64, 65, 73
13	July 09	General update for new S/W version (3.2.4). Correction in caution note regarding power supply. Corrections in installation of adaptor drivers. Updated patent information.	All	All
14	Jan 10	Probe expiration date	All	56

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Table of Contents

1	General Information.....	1
1.1	Intended Purpose of the Endo-PAT2000	1
1.2	Performance and clinical study information.....	1
1.3	Equipment Classification.....	3
1.4	Manufacturers Notice	3
1.5	Restrictions for Use	3
1.6	Quality Assurance System: ISO 9001 & ISO 13485	4
1.7	Conventions Used in this Manual.....	5
1.8	Safety Precautions	6
2	System Overview	8
2.1	How to Use this Manual.....	8
3	Installing the System.....	9
3.1	Basic System Configuration	9
3.2	System description.....	10
3.3	Connecting the Endo-PAT2000 to the Computer.....	11
3.4	Endo-PAT2000 Software Installation	12
3.5	Installing the RS-232 to USB adaptor.....	15
3.6	Uninstalling Endo-PAT2000 Software.....	16
3.7	Shutting Down the System	16

Itamar Medical Ltd.

4	Software Description	17
4.1	Main Screen	17
4.2	Main Screen Menu Commands	19
4.3	Main Screen Tool Bar	19
4.4	Configuring the System	21
4.5	Using the Timer (Countdown Clock).....	26
4.6	Setting the Default Printer	26
5	Preparing for a Study	27
5.1	Preparing the System for a Study.....	27
5.2	Connecting the PAT Probe	27
5.3	Creating a Patient File	28
6	Conducting an Endo-PAT2000 Study	31
6.1	Pre-Study	31
6.2	Patient and System Setup.....	33
6.3	Performing the Study	36
7	Review and Analysis	42
7.1	Study Data Retrieval	42
7.2	Automatic Analysis.....	43
7.3	Batch Analysis.....	47
7.4	Manual Analysis (Research Mode only)	48
7.5	Study report & printing.....	50
7.6	Uploading data to the server	50

Itamar Medical Ltd.

8	Maintenance.....	51
9	Troubleshooting	52
10	Technical Information	55
10.1	System Requirements	55
10.2	Operating System	55
10.3	Technical information about labeling.....	55
10.4	Labeling	57
10.5	10.5 Specifications for Endo-PAT2000	58
10.5	10.5 Specifications for Endo-PAT2000	59
	Appendix A: License Agreement and Limited Warranty	60
	Appendix B: Regulatory Authorized Representative.....	67
	Appendix C: installing the USB adaptor for Windows XP.....	68
	Appendix D: installing the USB adapter for Windows Vista.....	74

Itamar Medical Ltd.

List of Figures

Figure 1 - Typical set-up	9
Figure 2 - Endo-PAT2000	10
Figure 3 - Connection of pneumo-electric tubing and USB adaptor	11
Figure 4 - Install shield wizard	12
Figure 5 - License agreement	13
Figure 6 - Installation folder selection	13
Figure 7 – Ready to install the program screen	14
Figure 8 - Completion of installation	14
Figure 9 - Main screen	17
Figure 10 – Fill site name dialog box	18
Figure 11 - Gain and time-base scroll boxes	21
Figure 12 - The setup command	22
Figure 13 - The setup dialog box	23
Figure 14 – Report Appearance dialog box	24
Figure 15 - The example for report header	24
Figure 16 - The PATographer Information dialog box	25
Figure 17 - COM port search	27
Figure 18 - Inserting into slit	28
Figure 19 - Clicking in	28
Figure 20 - Press to release	28
Figure 21 - Probe disconnected	28
Figure 22 - Patient information dialog box (metric and US units)	30

Itamar Medical Ltd.

Figure 23 - File ID exists warning message	30
Figure 24 - Used probes warning	33
Figure 25 - Applying the PAT probes	35
Figure 26 - Hands set-up	35
Figure 27 - StandBy mode.....	37
Figure 28 - Recording.....	38
Figure 29 - Occlusion quality assessment	40
Figure 30 - Open file dialog box	42
Figure 31 - Automatic analysis.....	43
Figure 32 - Occlusion Popup Menu.....	46
Figure 33 - Marking Segments and Artifacts	49
Figure 34: MOXA USB Installation – XP1.....	68
Figure 35: MOXA USB Installation – XP2.....	69
Figure 36: MOXA USB Installation – XP3.....	69
Figure 37: MOXA Adapter	70
Figure 38: MOXA Adapter Configuration – XP2	70
Figure 39: MOXA Adapter Configuration – XP3	71
Figure 40: MOXA Adapter Configuration – XP4.....	71
Figure 41: MOXA Adapter Configuration – XP5	72
Figure 42: MOXA Adapter Configuration – XP6.....	72
Figure 43- connect MOXA adaptor.....	73
Figure 44 – connect COM TO COM.....	73
Figure 45: Windows Security Allowance.....	74
Figure 46: MOXA Uport driver installation.....	75

Itamar Medical Ltd.

Figure 47: MOXA driver installation folder.....	75
Figure 48: MOXA driver folder confirmation.....	76
Figure 49: MOXA driver installation finish.....	76
Figure 50: The MOXA Adapter	77
Figure 51- connect MOXA adaptor.....	78
Figure 52 – connect COM TO COM.....	78

List of Tables

Table 1 - Main screen pull down menu commands.....	19
Table 2 - Tool bar buttons and functions.....	20
Table 3 - table information (Note: fields <i>E</i> to <i>I</i> and <i>BO</i> will only appear in non-US and in research versions only)	45
Table 4 - Troubleshooting	53
Table 5 - Error messages	54
Table 6 - Specifications	59

1 General Information

This manual is part of the Endo-PAT2000 system.

1.1 Intended Purpose of the Endo-PAT2000

The Endo-PAT2000 device is a non-invasive device, intended for use as a diagnostic aid in the detection of coronary artery Endothelial Dysfunction (positive or negative) using a reactive hyperemia procedure.

The Endo-PAT2000 has been shown to be predictive of coronary artery Endothelial Dysfunction in the following patient population: patients with signs or symptoms of ischemic heart disease, who are indicated for coronary artery angiography, but who lack angiographic evidence of obstructive coronary artery disease. The device is intended to be used in a hospital or clinic environment by competent health professionals

The Endo-PAT2000 device is not intended for use as a screening test in the general patient population. It is intended to supplement, not substitute, the physician's decision-making process. It should be used in conjunction with knowledge of the patient's history and other clinical findings.

1.2 Performance and clinical study information

The following sensitivity and specificity data were revealed from a clinical study that was performed at the Mayo Clinic Rochester, MN and that had been designed to evaluate the safety and effectiveness of the Endo-PAT2000 as an aiding tool in the diagnosis of coronary artery Endothelial Dysfunction versus a Gold Standard for coronary Endothelial Dysfunction evaluation, the Intra-coronary Acetylcholine (Ach) Challenge method:

All subjects: Sensitivity = 82% (45/55), 95% lower confidence bound = 71%

Specificity = 77% (30/39), 95% lower confidence bound = 63%

Females: Sensitivity = 91% (30/33), 95% lower confidence bound = 78%

Specificity = 74% (17/23), 95% lower confidence bound = 55%

Males: Sensitivity = 68% (15/22), 95% lower confidence bound = 48%

Specificity = 81% (13/16), 95% lower confidence bound = 58%

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The Gold Standard for Endothelial Dysfunction evaluation, the Intra-coronary Acetylcholine (Ach) Challenge method, is routinely performed at the Mayo Clinic.

According to the Intra-coronary Acetylcholine (Ach) Challenge method, a catheter is positioned in the origin of the left main coronary artery and Ach is infused with incremental concentration followed by coronary angiogram. The coronary artery diameter is measured in the segment 5mm distal to the tip of a Doppler wire using a computer-based image analysis system. Average peak velocity (APV) is derived from the Doppler flow velocity spectra and coronary blood flow (CBF) is determined as: $\pi \cdot (\text{coronary artery diameter}/2)^2 \cdot (\text{APV}/2)$. Endothelium-dependent coronary flow reserve is calculated as percent change in CBF in response to the Ach challenge.

Normal coronary endothelial function is defined as an increase in CBF of >50% and an increase or less than 20% decrease in the coronary artery diameter in response to the maximum dose of intra-coronary Ach ($\Delta\text{CBF} > 50\%$ and $\Delta\text{CAD} > -20\%$)

[Al Suwaidi J, Hamasaki S, Higano ST, Nishimura RA, Holmes DR Jr, Lerman A. **Long-term follow-up of patients with mild coronary artery disease and endothelial dysfunction.** *Circulation* 101:948-954, 2000]

Synopsis of Clinical Study Protocol:**Objectives:**

To evaluate the Endo-PAT2000 relative to a gold standard procedure as a diagnostic aid for detecting coronary endothelial dysfunction.

Methodology:

Patients, who had been referred to diagnostic angiography cardiac catheterization laboratory for diagnostic angiography secondary to signs or symptoms of ischemic heart disease and suspected coronary endothelial dysfunction and were found to have normal or near to normal angiogram, underwent Intra-coronary Acetylcholine (Ach) challenge test to assess attenuation in required increases to coronary blood flow (CBF) and coronary artery diameter (CAD), where each of these parameters served as an indicator for coronary endothelial dysfunction. Coronary endothelial dysfunction is diagnosed if one of the following changes is observed in response to the Ach challenge test: $\Delta\text{CBF} \leq 50\%$ OR $\Delta\text{CAD} \leq -20\%$. Patients were then evaluated using the Endo PAT 2000, which measures Peripheral Arterial Tone (PAT) signal changes at the fingertip, to a reactive hyperemia challenge. The PAT signal is a measure of the digital pulsatile volume changes and is measured with a non-invasive disposable PAT probe. The reactive hyperemia procedure consists of a 3-10 minute baseline recording, 4.5-5.5 minutes of blood flow occlusion to one arm using an upper arm blood pressure cuff, and 3-5 minutes of recording after cuff release. The expected response is of a post occlusion increase of the PAT signal amplitude and the PAT score is provided automatically by the system's software and is basically the ratio between the post- to pre- occlusion average signal size, corrected for systemic changes and baseline level.

Planned Enrollment: 100 patients

Actual Enrollment: 111

Safety Analysis Cohort: 110 (One patient withdrew consent)

Efficacy Analysis Cohort: 94

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Criteria for inclusion:

- Patient Age > 17
- Patient referred to diagnostic angiography
- Normal or near normal angiogram (< 30% stenosis)
- Evaluation in catheterization laboratory
- Signed informed consent

Criteria for exclusion:

- Deformities of fingers that preclude adequate signal acquisition with the Endo-PAT2000.
- Short acting NTG less than 6 hours prior to study and calcium channel blockers or alpha-blockers less than 24 hours prior to study.

1.3 Equipment Classification

The Endo-PAT2000 is classified as a Class IIa medical device in accordance with Rule 10 of Annex IX of the Medical Device Directive 93/42 EEC, 2007/47/EC

According to IEC 60601-1 / UL 60601-1 Endo-PAT2000 is classified as Class II medical device.

1.4 Manufacturers Notice

The information in this document is subject to change without notice.

Itamar Medical Ltd. makes no warranty of any kind on this material, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Itamar Medical Ltd. shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

This document contains proprietary information, which is protected by copyright. All rights reserved. No part of this document may be photocopied, reproduced, or translated without the prior written consent of Itamar Medical Ltd.

1.5 Restrictions for Use

- Only qualified medical personnel may authorize the use of the Endo-PAT2000.
- In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
- The eligibility of a patient for a PAT study is generally based upon the patient's medical status. The following should not be considered for the PAT study:

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- Deformities of the digits of the upper extremities, which preclude adequate signal acquisition
- Patients under the effect of short-acting NTG (3 hours washout period)
- The Endo-PAT2000 system in whole, or in part, may not be modified in any way.
- The device is intended for diagnostic purposes only, and should not be used for monitoring.
- The device is not intended as a screening test in the general patient population.
- Itamar Medical Ltd. makes no representation whatsoever, that the act of reading this User Manual renders the reader qualified to operate, test or calibrate the system.
- The tracings and calculations provided by the Endo-PAT2000 system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
- In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this manual, the operator should refer to the **Troubleshooting** section. If necessary, contact our service office to report the incident, and to receive further instructions (customer support can be reached at +972-4-617 7000 ext. 399, or from the US: (800) 206 6952 ext. 399).

1.6 Quality Assurance System: ISO 9001 & ISO 13485


	STANDARD	#
1.	Medical electrical equipment- general requirements for safety	IEC 60601-1
2.	Medical electrical equipment electromagnetic compatibility	IEC 60601-1-2
3.	Programmable electrical medical system Requirements for safety	IEC 60601-1-4
4.	Quality systems - Model for quality assurance in design, development, production, installation and servicing	ISO 9001:2008
5.	Quality systems medical devices	ISO 13485:2003
6.	Risk Analysis for Medical Device	ISO 14971
7.	Labeling Medical Devices	EN 980
8.	Medical Device Directive	MDD 93/42 EEC


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		MDD 2007/47/EC
9.	Quality systems - Medical devices - System requirements for regulatory purposes (Health Canada)	CAN/CSA ISO 13485:1998
10.	CSA standard for safety	CSA 22.2 No. 601.1
11.	UL standard for safety	UL 60601-1
12.	Canadian Medical Devices Regulations	SOR/98-282

1.7 Conventions Used in this Manual

The following conventions are used throughout this manual:

	<p style="text-align: center;">Warnings</p> <p>Are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or could cause damage/malfunction of the system, resulting in the irretrievable loss of data.</p>
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	<p style="text-align: center;">Cautions</p> <p>Are used to identify conditions or actions that could cause interference with data acquisition and/or impair study results.</p>
---	---

	<p style="text-align: center;">Notes</p> <p>Are used to identify an explanation, or to provide additional information for purposes of clarification.</p>
---	---


There are no additional warnings and cautions, other than those provided in the appropriate sections of this manual.


Physicians, nurses, and medical technicians should read the Endo-PAT2000 Operation Manual carefully, before operating the system.

All pictures are for illustrative purposes only.

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1.8 Safety Precautions


	<p style="text-align: center;">WARNING</p> <p>Only the power supply that is provided within the EndoPAT-2000 package will be used for the system.</p> <p>Use of an inappropriate adapter may cause irreparable damage to the device and may compromise patient safety.</p>
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	<p style="text-align: center;">WARNING</p> <p>The Endo-PAT2000 should only be installed with and connected to computer equipment that complies with EN60950 safety regulations.</p> <p>Failure to heed these warnings may compromise patient safety.</p>
---	---

1. The Endo-PAT2000 has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum operation safety the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this manual.
2. The system contains no user-serviceable parts. It should be maintained and serviced only by qualified service personnel, authorized by Itamar Medical Ltd.
3. Purchasers of the Endo-PAT2000 should ensure that only suitably trained, qualified personnel are authorized to operate the equipment. Unauthorized personnel should not be allowed access to the system. It is recommended that a list of authorized operators be maintained.
4. The Endo-PAT2000 Operation Manual should be carefully studied by the authorized operators, and stored where it is easily accessible. Periodic review of the manual is recommended.
5. The Endo-PAT2000 is a whole system. To eliminate risk of electrical shock, do not attempt to open or remove system covers or plugs.
6. Do not operate or activate mobile phones, or other devices capable of causing electro-magnetic interference, nearby the system.
7. Avoid placing liquids or food on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system as this may cause a short circuit, which could result in an electrical fire. In this event, only fire extinguishers approved for use on electrical fires should be used.

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8. Do not allow fluids to come in contact with the pneumatic connection in the device.
9. Do not operate the equipment in the presence of explosive liquids, vapors or gases.
10. In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this manual, the operator should contact customer support.
11. Do not apply the probe to an infected finger or wounded skin.

	<p style="text-align: center;">Caution</p> <p>Federal law restricts this device to sale by or on the order of a physician.</p>
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	<p style="text-align: center;">WARNING</p> <p>Probes manufactured before January 2007 contain 50 micrograms or less per gram of natural rubber latex water extractable protein which may cause allergic reactions. Do not use the latex probes on patients who have a known natural rubber protein allergy. Failure to heed this warning will compromise patient safety.</p> <p>The latex probes have a yellow membrane and come in boxes with labels notifying that they contain latex.</p> <p>The new, non-latex probes have green internal membranes.</p>
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2 System Overview

The Endo-PAT2000 is a computer-based system for non-invasively assessing vascular endothelial dysfunction. It is based on the use of Peripheral Arterial Tone (PAT) signal technology, during a clinically established procedure, which measures post-ischemic vascular responsiveness following upper arm blood flow occlusion.

PAT signal technology is a newly developed proprietary technology for measuring the magnitude and dynamics of arterial tone changes in peripheral arterial beds. PAT technology measures peripheral arterial tone, by recording digital pulsatile volume changes without involving painful and risky invasive procedures.

The non-invasive PAT probe, used with the Endo-PAT2000, is a new type of finger plethysmograph that imparts a uniform pressure field to the distal two thirds of the finger including its tip. It was designed to avoid many of the existing problems associated with conventional plethysmographic devices such as distal venous distention and the resulting induction of reflex veno-arteriolar constriction, and it has a higher dynamic range of changes and better clamping to the finger. Its extended pressure field also excludes spurious venous signals while continuously recording the digital arterial pulse wave.

Studies using the Endo-PAT2000 are easily performed in any clinical setting, with a minimal period of training required. The system is fully computerized and the recorded signals are simultaneously displayed on a PC or laptop screen. Recorded data is automatically saved, facilitating subsequent review and computerized automatic analysis. Due to the fact that analysis is performed automatically, there is no question of inter or intra operator interpretation variability.

The PAT software program is easy to use and has two main operating phases:

- Real time recording and display
- Off-line display and analysis

Since the system records data in real time, it is possible to follow events as they occur.

Data acquired during a study is automatically stored to the computer's hard disk and may subsequently be retrieved for off-line review and automatic analysis.

2.1 How to Use this Manual

This Operation Manual is designed as a general guide to help the user in operating the system. The user will find step-by-step instructions for performing a PAT study, and instructions for maintenance of the system.

3 Installing the System

3.1 Basic System Configuration

The Endo-PAT2000 is supplied as a complete package comprising the following components:

- One Endo-PAT2000 device
- One Endo-PAT2000 software CD
- Three pneumo-electric tubing (2 tubes + 1 spare)
- Power adaptor
- Power cable
- Operation manual
- Set of 6 foam finger anchors

The supplied Endo-PAT2000 software package can be used with any IBM-compatible computer running English versions of Windows XP and Windows Vista. The automatic analysis module requires any type of internet browser or Excel 2000/2003.

For details regarding hardware and software requirements, refer to System Requirements in Section 10.1.

Although individual system set-ups may vary, Figure 1 represents a typical setup of a study.



Figure 1 - Typical set-up

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3.2 System description

The Endo-PAT2000 device top panel has:

- Power LED indicator
- LED indicator for the device-computer communication status
- Probe's Deflate and Inflate buttons



Figure 2 - Endo-PAT2000

The front panel has two pneumatic input connectors for attaching the pneumo-electric tubing, connecting the PAT probes to the Endo-PAT2000 device.

The back panel has (Figure 2):

- Power supply DC connector
- Communication port
- ON/OFF switch

Itamar Medical Ltd.**3.3 Connecting the Endo-PAT2000 to the Computer****NOTE**


The Endo-PAT2000 system requires the use of a USB to Serial adapter. The Endo-PAT2000 can alternatively be connected to a serial (COM) port in the computer with a standard 9-pin RS232 cable.

1. Place the Endo-PAT2000 and computer in close proximity to the examination bed or chair. The device should be placed at a distance from the bed or chair that is shorter than the pneumo-electric tubing (less than 1.8 meters/ 6 feet).
2. Connect the USB-to-COM adapter to the communication port on the Endo-PAT2000, and to one of the computer's USB ports. Hand-tighten the screws to secure the adaptor (see Figure 3). In case RS232 cable is used connect it to both Endo-PAT2000 and computer and tighten the connecting screws.
3. Connect both pneumo-electric tubing to the Endo-PAT2000 front panel pneumo-electric connectors and secure by hand tightening the screws (see Figure 3).
4. Make sure the power switch is off. Connect the power supply first to the Endo-PAT2000 and then to an electrical outlet. Turn the power switch on.
5. The power indicator light will glow orange, indicating that the power is turned on.




Figure 3 - Connection of pneumo-electric tubing and USB adaptor

Itamar Medical Ltd.**3.4 Endo-PAT2000 Software Installation**

	<p style="text-align: center;">NOTE</p> <p>Prior to software installation, verify that you are in full system administrator mode with full privileges. Otherwise, the installation might not succeed and could cause operational problems.</p>
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1. Close all open applications operating on the computer, including background applications, before installing the Endo-PAT2000 software.

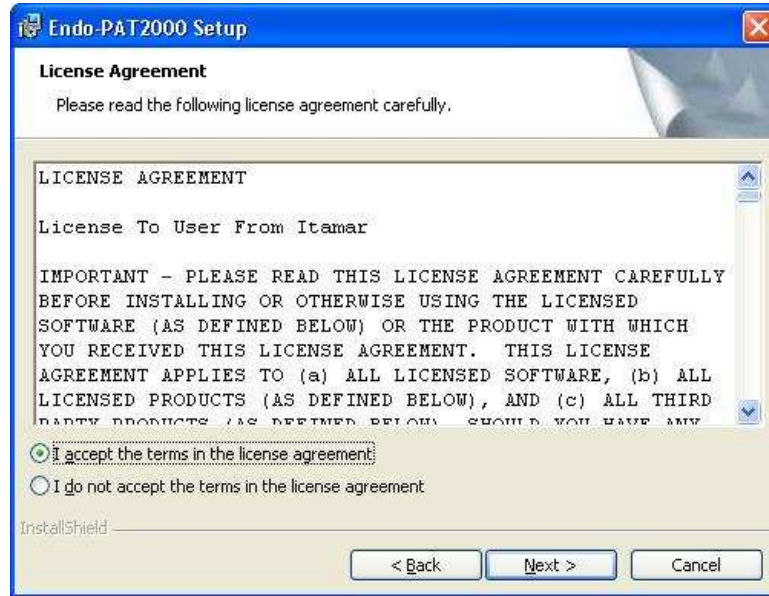
	<p style="text-align: center;">NOTE</p> <p>Uninstall previous Endo-PAT2000 software versions prior to installing a newer version. To uninstall the software please refer to section 3.6.</p> <p>Make sure to backup all your data prior to uninstalling any software.</p>
---	--

2. Insert the Endo-PAT2000 software CD into the computer drive. The installation program will load automatically. Alternatively the user may select the 'setup.exe' command from the CD drive.
3. The Install Shield prepares the computer for installation. When prompted, click next to proceed with the installation (Figure 4).

**Figure 4 - Install shield wizard**

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4. Read the license agreement and select the “I accept” option to agree to its terms and continue with the installation by pressing “next” (Figure 5). Click “I do not accept” if you do not accept the terms of the agreement and wish to abort the installation.

**Figure 5 - License agreement**

5. Click “Next” to set the default target folder for software installation, or click “Change” to select a different folder for the installation (Figure 6).

**Figure 6 - Installation folder selection**

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	<p style="text-align: center;">NOTE</p> <p>It is not recommended to install the program in the “My Documents” or “Desktop” folders.</p>
---	--

6. Press “Install” to complete the installation process or “Back” to review or change any of your installation settings” (Figure 7).

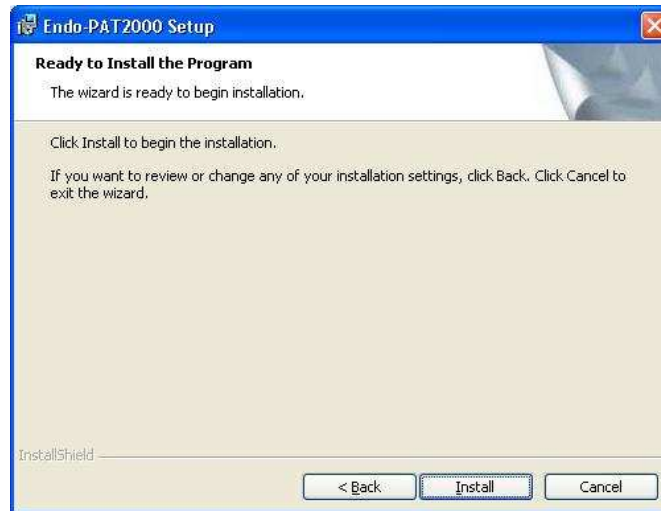


Figure 7 – Ready to install the program screen

7. Press “Finish” when the installation is complete (Figure 8).

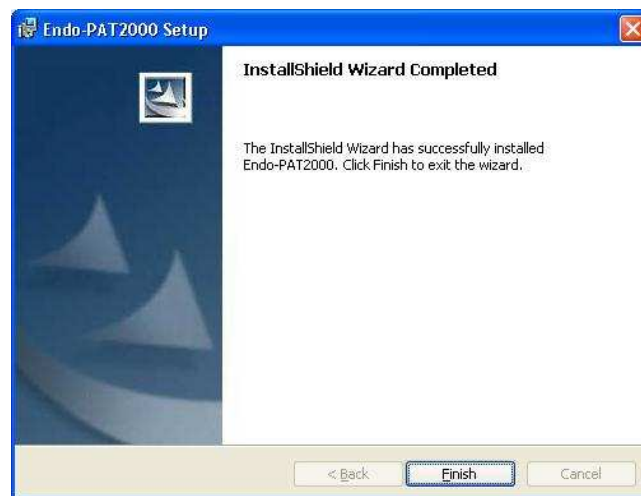


Figure 8 - Completion of installation

8. An icon will be added to the desktop.
9. If used, install the USB-to-COM driver as described in section 3.5.

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3.5 Installing the RS-232 to USB adaptor

The RS-232 to USB adaptor connects the Endo-PAT2000 device to the computer's USB port. The adapter kit contains the adapter and a software installation CD with the appropriate drivers for Windows XP and for Windows Vista.

The installation process depends on your computer's operating system. Please refer to Appendix C for instructions on how to install the driver on Windows, or to Appendix D for instructions on how to install the driver on Windows Vista Enterprise.

3.5.1 General instruction for installing the driver

1. The driver installation must be done before connecting the RS-232 to USB adaptor to the computer.
2. Insert the CD into the CD-ROM drive
3. Browse into the CD-ROM drive
D:\Your_OS\SETUP
4. Execute the Driver's .exe file
5. Continue the installation process by clicking 'next' until installation ends
6. Connect the RS-232 to USB adapter to the computer.

**Note**

Restart your computer after installation of the Endo-PAT2000 software and the RS-232 to USB adaptor driver.

When the driver installation is completed, connect the USB adaptor to the computer and start the Endo-PAT2000 software (refer to section 4). The software will search for the appropriate communication port to communicate with the connected RS-232 to USB adaptor as described in section 5.1.

**Note**

Refer to the configuration section (Section 4.4) for setting the configuration of the COM port.

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3.6 Uninstalling Endo-PAT2000 Software


Enter the computer's Control Panel and select the Add/Remove programs option. Select the Endo-PAT2000 software and press "remove".

3.7 Shutting Down the System

1. Shut down the Endo-PAT2000 software program by selecting the Exit on the pull down File menu.
2. Switch OFF the Endo-PAT2000 device using the on/off switch on the back panel.

4 Software Description

4.1 Main Screen

From the Windows™ desktop double click the  icon. The following screen will appear (see Figure 9).

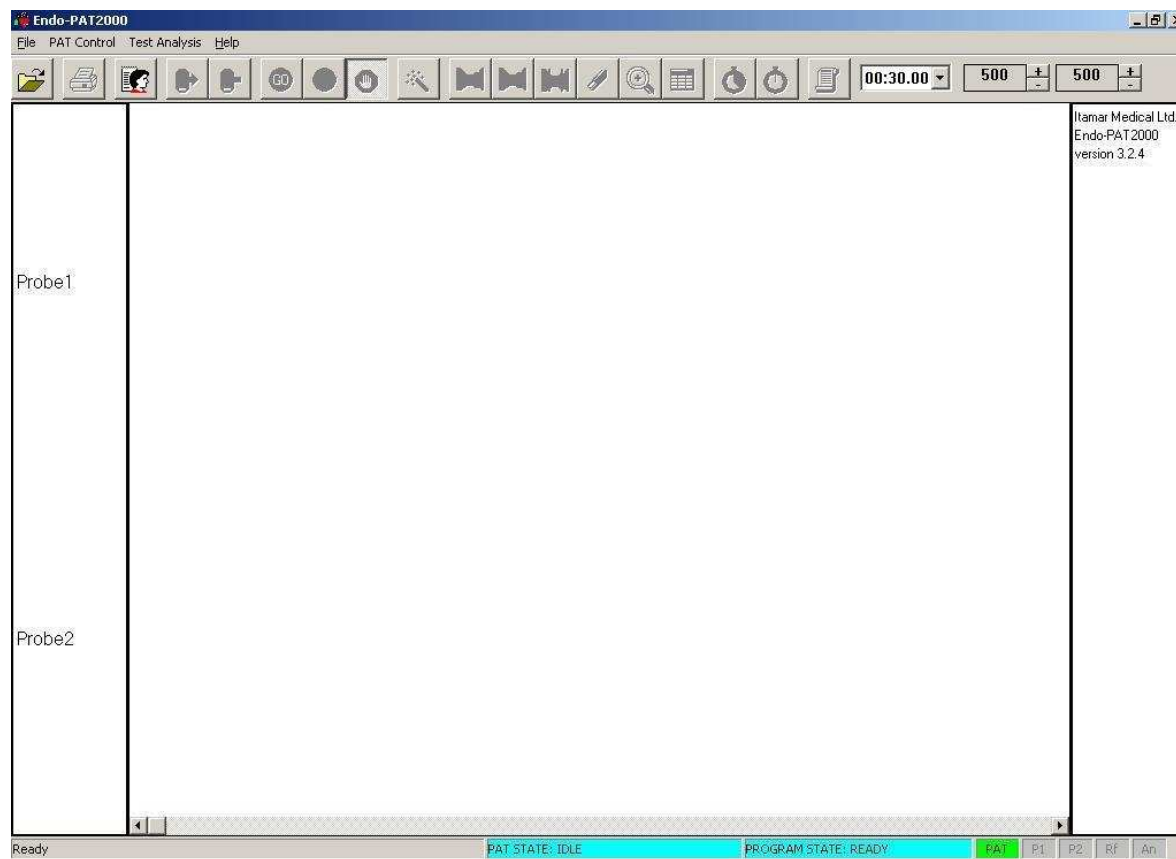


Figure 9 - Main screen

The Main Menu Screen is the gateway to the functions of the Endo-PAT2000 software. The three primary functions are: perform a study, review and analyze a study and system configuration.

The main screen includes:

1. Interfaces:

- Pull-down menu bar (section 4.2)

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- Tool bar (section 4.3)
- Scroll bar (section 4.3.2)

2. Display windows:

- Channels identification column (for the PAT waveforms and Trend traces)
- PAT waveforms and Trend traces window
- Results/calculations column

3. Status bar:

- PAT state (communication status between PAT device and computer)
- Program status
- Probe status

When first launching the Endo-PAT2000 software, a dialog box (Figure 10) will open. Click the OK button to enter the Setup menu. Complete the setup as described in section 4.4.



Figure 10 – Fill site name dialog box

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4.2 Main Screen Menu Commands

Table 1 describes the main screen pull-down menu commands:

Menu Item	Function
File	Open a previously-saved study Save study data Print screen Exit the Endo-PAT2000 Software
PAT Control	Inflate PAT probes Deflate PAT probes Stop a study Standby mode - view signals without recording GO - Start recording a study Start Timer Reset Timer Setup parameters
Test Analysis	Open Patient Information dialog box Automatic Analysis Select occlusion period Select Baseline Segment (in Research mode only) Select Test Segment (in Research mode only) Mark segment as artifact (in Research mode only) Clear all marked segments Zoom In View report Open Batch Analysis dialog box
Help	Provides access to system information Link to Itamar Medical Uploading Service

Table 1 - Main screen pull down menu commands

4.3 Main Screen Tool Bar

The Main Screen tool bar buttons provide quick access to selected menu commands, opens result table, and to the Gain and Timing settings. Gain and Timing settings are used to adjust the Trace Window display.

Dimmed icons indicate that they are not active and cannot be used unless some actions are taken. For example the automatic analysis icon is not active unless there is a data file displayed and ready to be processed.

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Table 2 lists each button and its function. “Mouse over” a button to trigger bubble help describing the button’s function.

Button	Function
	Load file
	Print screen
	Open Patient Information Dialog Box
	Deflate PAT probes
	Inflate PAT probes
	Start study
	Standby
	Stop study
	Automatic Analysis
	Mark segment as B (in Research mode only)
	Mark segment as T (in Research mode only)
	Mark segment as artifact (in Research mode only)
	Clear all segments
	Zoom In
	Open result of last calculation
	Start/Stop timer
	Reset timer to the value set in the Setup dialog box
	View Report
	Set time base and gains

Table 2 - Tool bar buttons and functions

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4.3.1 Gain and Time-base trace display Tools

Use the Gain command, to adjust the Trace Window display.



Figure 11 - Gain and time-base scroll boxes

The two gain tools adjust the traces' display of the PAT 1 and PAT 2 channels (The scroll boxes are in order from left to right: left is probe1 and right is probe2). Adjustments made to the PAT channel gain settings affect only the display of the corresponding trend channels.

	<p style="text-align: center;">NOTE</p> <p>Adjusting gain or time-base settings affects only the display and not the recorded signal, even during the recording.</p>
---	---

To adjust the Gain Setting, click the + or - sign next to the appropriate Gain Tool channel. The gain display setting is increased (+) or decreased (-) and the new setting takes effect accordingly.

To Adjust a Time Base Setting, click the Timing pull-down menu and select the desired time base setting. The time scale adjustment is automatic. When a file is open, an **All Study** option is available, allowing to automatically select the nearest time base interval that exhibits the entire study's data on screen.

4.3.2 Scroll Bar

Use the horizontal scroll bar and left and right scroll arrows at the bottom of the Trace Window to view the entire study. Scroll to the left to move backwards, and scroll to the right to move forward.

As trace data appears in the Display Window, the data is saved in the Patient Information file. The study can be analyzed and reviewed off-line in either relative or absolute time modes.

4.4 Configuring the System

The Set-up menu is used to configure the system. To ensure that the Endo-PAT2000 is ready for operation, the configuration of the signal channels and serial port is required.

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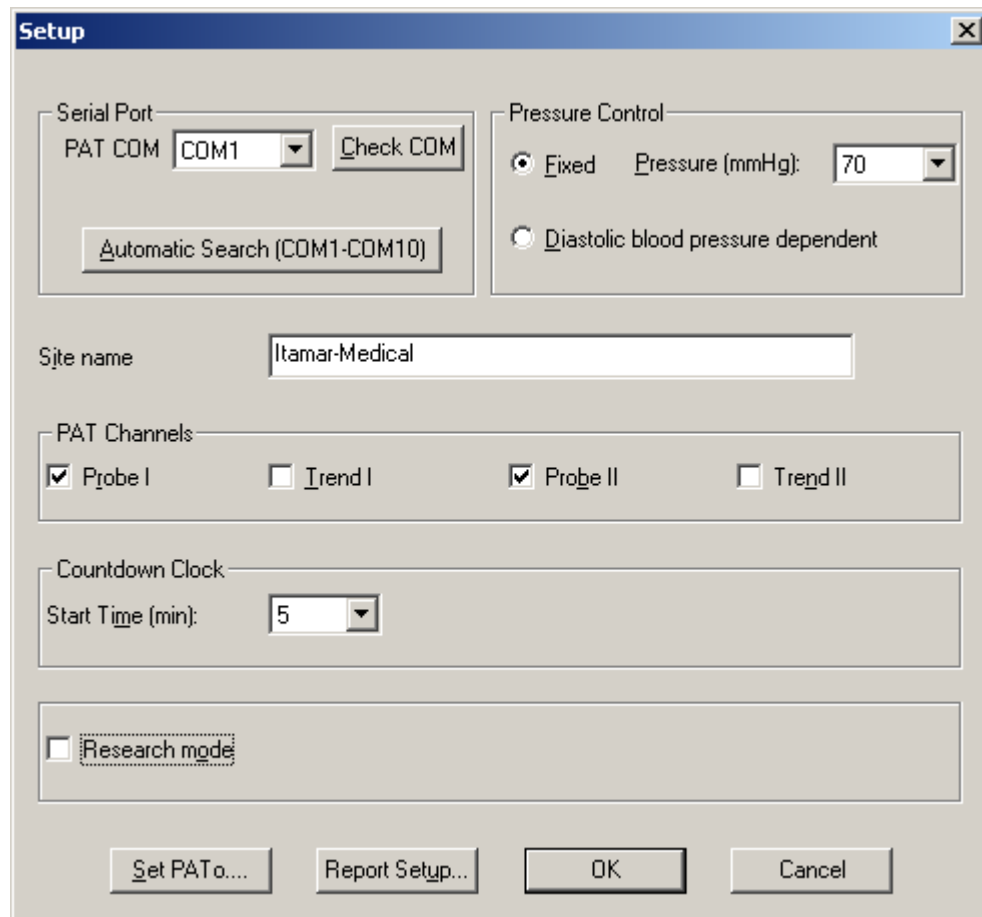
To Configure the System:

1. Verify that the Endo-PAT2000 is properly connected to the PC and that it is switched on.
2. Click PAT Control, and then click Setup.



Figure 12 - The setup command

3. The following screen will appear:

Itamar Medical Ltd.**Figure 13 - The setup dialog box**

4. Click “Automatic Search (COM1-COM10)” to allow the system to automatically identify the COM port to which the Endo-PAT2000 is connected.
5. If the automatic search fails, you can select or type the correct COM port for the Endo-PAT2000 manually in the relevant field. After selecting the desired COM port verify communication by clicking “Check COM”.
6. In the “PAT Channels” frame, select which channels should be displayed on screen. For normal operation both PAT channels should be selected.
7. The Countdown Clock (timer) is set to “5” minutes by default. To change this value (1 through 15), select the appropriate value from the drop-down menu.
8. To enable the Research mode, select the “Research mode” checkbox. The entire “Test analysis” menu is enabled.
9. To configure the report press the “Report Setup” button. This will open the “report appearance” dialog. In this dialog the Clinic details (a logo and 3 text lines) can be updated. These details will be used as a header to all Endo-PAT reports. Notice that the logo size is limited: big images will be reduced to fit the page.

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Each of the 3 lines can contain up to 70 characters.

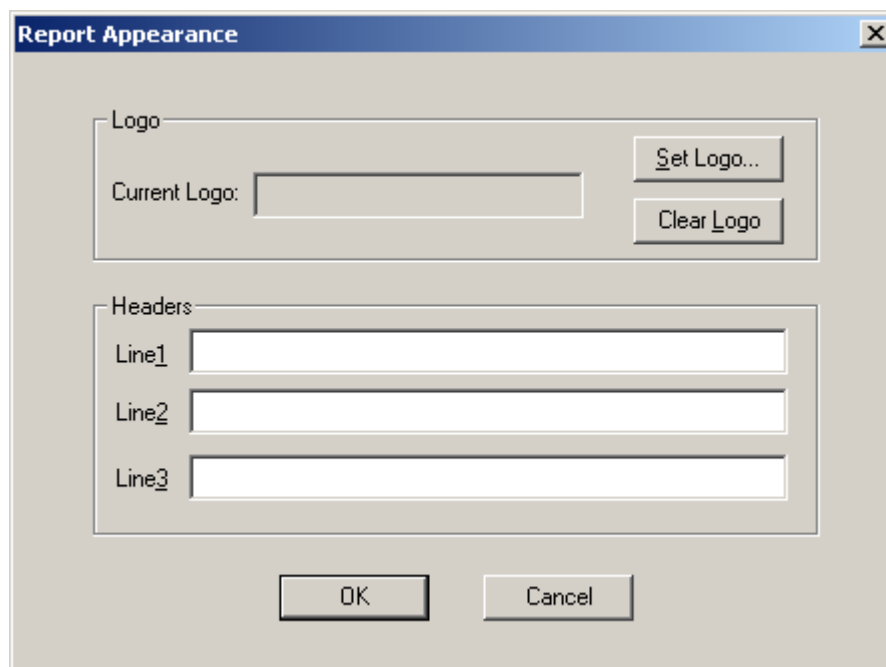


Figure 14 – Report Appearance dialog box

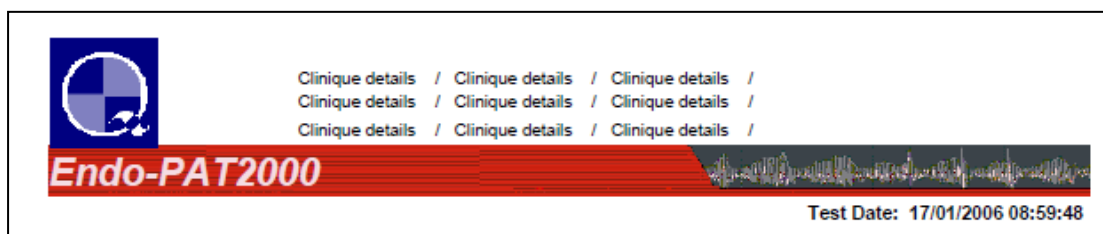
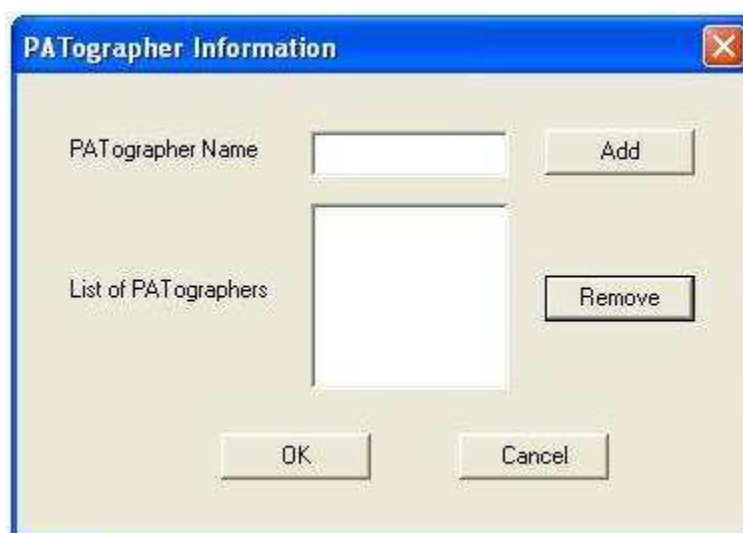



Figure 15 - The example for report header


10. The name of the operator performing the Endo-PAT2000 study can be saved with the study data. To create the master list from which the names are selected, click the “Set PATographer” to open the following dialog box:

Itamar Medical Ltd.**Figure 16 - The PATographer Information dialog box**


11. Type the names of the PATographers in the top field and click “Add” after each one is entered. When you finished entering all the names, click “OK” to save the information and exit. Click the “Cancel” button to exit without saving the changed information. You can remove unused names by selecting a name in the bottom field and clicking “Remove”.
12. In the “Pressure control” frame select whether the probe inflation pressure is set to a pressure that is dependent on the patient’s diastolic blood pressure (recommended mode) or to a fixed pressure.
13. If a fixed pressure setting is selected, the inflation pressure can be changed from the default 50mmHg.

	<p style="text-align: center;">NOTE</p> <p>If “Diastolic blood pressure dependent” is selected, the diastolic blood pressure of the patient must be entered prior to commencing the study. The study cannot start without this information.</p>
---	--

14. When all the settings are correct, click OK.

	<p style="text-align: center;">NOTE</p> <p>The default inflation pressure setting for the PAT Sensors is 50 mmHg in “fixed” mode. It is recommended that this is not exceeded, unless specified otherwise.</p>
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	<p style="text-align: center;">NOTE</p> <p>Setup can be opened while recording a study, to select which signals are displayed. However, during a recording the COM field and the Pressure Control fields are disabled and cannot be modified.</p>
---	--

4.4.1 Switching to the Research Mode

1. From the “PAT Control” menu, select the “Setup...” option.
The Setup window is displayed.
2. In the Setup window, select the “Research mode” checkbox; then, click “OK”
(Refer to Figure 13).

4.5 Using the Timer (Countdown Clock)

Some phases in the study recording require strict timing. To operate the timer, refer to the following instructions:

- **To set the timer** (the number of complete minutes it will count), refer to the Setup menu (section 4.4)
- **To start the timer**, click the  icon. When the timer reaches “0”, the timer indicator at the bottom right of the screen blinks red.
- **To stop the timer**, click the  icon again. The timer stops counting.
- **To restart the timer**, click the  icon. The timer resets and starts counting, according to the set-up in the setup screen.

4.6 Setting the Default Printer

Setting the default printer is performed in the normal manner by accessing the Printer Setup window from the Windows™ desktop.

5 Preparing for a Study

5.1 Preparing the System for a Study

Accessories that are required beside the Endo-PAT2000 system:

- A set of two PAT probes and anchors
 - Blood pressure cuff (capable of sustaining high pressures for 5 minutes)
 - Adhesive tape
 - Pair of arm supports
 - Timer/stopwatch
1. Switch on the computer, the Endo-PAT2000 device, and launch the Endo-PAT2000 software with the shortcut icon on the desktop. When the Endo-PAT2000 software is launched it performs an automatic COM port search and communication test with the device. If the software is unable to establish communication with the device, a COM-port search dialog box will open (Figure 17). While this dialog box is open the system continues trying to establish communication with the device, going through COM ports 1 to 10 in a cyclical manner. This continues until communication is established or “Work Disconnected” is selected.

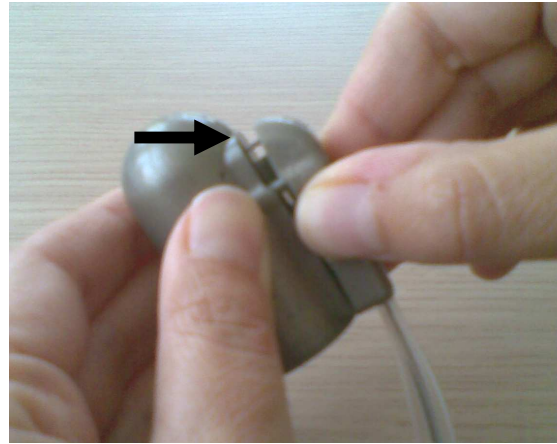


Figure 17 - COM port search

5.2 Connecting the PAT Probe


Connect two new probes by inserting the connector tab into each probe slit (see Figure 18) and pressing the connector down onto the probe until the tab of the probe clicks into place (see Figure 19).

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**Figure 18 - Inserting into slit****Figure 19 - Clicking in**

To remove probes, press the tab (clip) marked by the arrow in Figure 20, and then lift the connector away from the probe (Figure 21). Used probes should be disposed of properly.

**Figure 20 - Press to release****Figure 21 - Probe disconnected****5.3 Creating a Patient File**

- 1 Click the  icon on the tool bar or activate from the Test Analysis menu the Patient Information dialog box. (See Figure 22)
- 2 All mandatory fields must be filled in order to proceed to the next step. The field description is as follows:
 - Patient ID - Enter patient identification number (mandatory field).

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- Patient First and Last name - Enter the patient's complete name, initials or other identifier, or it can be left empty (optional field).
- Age - Enter the patient's age. This can be done manually, or by pressing the arrow key until the correct age appears in the window (mandatory field).
- Gender - select either male or female (mandatory field).
- Patient Height and Weight. Mandatory fields. Units are set according to the computer defaults – either centimeters and Kg or feet-inch and lbs.
- Diastolic Blood Pressure – mandatory field, unless the “Fixed pressure” mode was selected in the set-up screen (Figure 13).
- Systolic Blood Pressure – mandatory field.
- Comments - optional field.
- User Field 1 (Temp.) - optional field. Up to 10 characters length of free text. Designed to enter the room temperature at the beginning of the test.
- User Field 2 (Nails) - optional field. Up to 10 characters length of free text. Designed to enter the patient’s nail length – OK or over 5 mm/one fifth of an inch, beyond the tip of the finger tissue.
- PATographer - optional field - select from the pick list, or type directly into the field the name of the PATographer to be associated with the study.

**NOTE**

Study data is saved in a data file that is automatically named with the **Patient ID** number. If the patient ID is for example 12345, then the file name will be 12345.s32.

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Figure 22 - Patient information dialog box (metric and US units)

After clicking OK the Patient Information dialog box will close.

	<p style="text-align: center;">NOTE</p> <p>The computer's filing system will not allow the same Patient ID number for 2 different PAT studies. Designate new Patient ID's for the same patient by amending the original Patient ID number with sequential letters. For example—123456a, 123456b, etc.</p>
--	--

When trying to use an existing ID number, the following message appears:

**Figure 23 - File ID exists warning message**

A different ID must be entered before you can proceed.

6 Conducting an Endo-PAT2000 Study

6.1 Pre-Study

6.1.1 General description

The Endo-PAT system is comprised of a system console and two independent sensing probes coupled to connecting pneumo-electric tubing and foam finger mounting rings. The system console is connected to a computer loaded with a specific program for controlling the Endo-PAT system. The system console has two separate external switches for inflating and deflating the probes. The probes can be inflated and deflated via the computer program as well.

The probes' pressure and the setting of displayed signals are configured through the setup function in the "PAT Control" pull down menu (see Figure 12). Signal gain and time base are set through icons appearing on the Tool Bar (see section 4.3.1).

If the probes' pressure mode was initially configured to a "fixed pressure", then the recommended pressure setting is 50mmHg.

The eligibility of a patient for a Endo-PAT study is entirely at the discretion of the patient's physician, and is generally based upon the following criteria:

- Symptoms and complaints
- Medical history
- Risk factors
- Current medication
- Restrictions on use (Section 1.5)

6.1.2 System warm up

The system should be turned on and allowed to warm up for at least 20 minutes before commencing patients' studies. It is recommended that the system would not be turned off until the last study for the day has been completed.

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6.1.3 Pre-study adaptation period

Thermoneutral room temperature must be maintained at all times: 21°C-24°C (70°F-75°F).

Any restrictive clothing that could interfere with blood flow to the arms should be removed. Heavy coats or clothes with thick sleeves should not be worn. Watches or rings or other jewelry on the hands and fingers should be removed.

The upper arm blood pressure cuff should be applied snugly, but without excess pressure, which might hamper venous blood return, causing venous pooling in the arm (which is deleterious to the test performed).

The patient should then be comfortably seated or allowed to lie down in the study room and relax for at least 15 minutes or a sufficient period to reach a relaxed cardiovascular steady-state and to adjust to the room temperature.

6.1.4 Patient blood pressure measurement

The blood pressure measurement procedure may affect the vascular conditions of the patient. Therefore, if blood pressure measurement needs to be taken prior to the Endo-PAT study, the following should be considered:

- The blood pressure should be measured from the patient's control arm (the arm that is not occluded during the Endo-PAT study).
- It is recommended to allow 5 minutes to pass between the time of the blood pressure measurement and the commencement of the Endo-PAT baseline recording.

6.1.5 Positioning the patient


The patient should sit or lie down comfortably. In either case the patients' hands must be supported at approximately heart level.

6.1.6 Preparation of fingers and hands before a study

The finger should be inspected for any deformations or injuries that could affect the study. The probe should not be used on a finger that is cut, injured or unusually sensitive. Fingernails should be trimmed and filed if necessary to avoid damaging the internal membranes of the PAT probes & displaces the finger from the sensing region of the probe, resulting in a smaller PAT signal and inaccurate results. The index finger is the recommended finger for the study, however if this finger is too large to comfortably fit into

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the probe or is otherwise unsuitable (see above), a different finger (except the thumb) may be used, as long as it is the same finger in both hands.

	<p style="text-align: center;">WARNING</p> <p>Long nails may cause distorted PAT signals and may cause the study to fail.</p>
---	--

Before inserting the fingers into the probes, ensure all heavy clothes, tight fitting sleeves, rings, watches, and jewelry were removed from the patient's hands and arms.

6.2 Patient and System Setup

6.2.1 Study conditions

The study should be conducted in a quiet and relaxed atmosphere. Phones, beepers and other devices which can cause startling noises should be turned off; otherwise the startle effect on the patient might affect the test result. The patient should be kept comfortable and fully relaxed and asked to refrain from talking. Staff should avoid talking to the patient and between themselves as much as possible. These conditions should be kept throughout the entire study.

6.2.2 Initializing the PAT system


Activate the Endo-PAT2000 application. Enter patient details as required. Please note that the ID should be specifically assigned to the subject and is going to be allocated as the file name for the recorded PAT study.

Ensure that the pneumo-electric tubings are properly connected to the Endo-PAT2000 device, and a new set of probes is installed and ready for use. If the probes are not new, when you try to inflate the probes a warning dialog-box (Figure 24) will open.





Figure 24 - Used probes warning


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	<p style="text-align: center;">WARNING</p> <p>The probes are single use and disposable: they will not work properly, if they have already been used!</p>
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6.2.3 Patient preparation

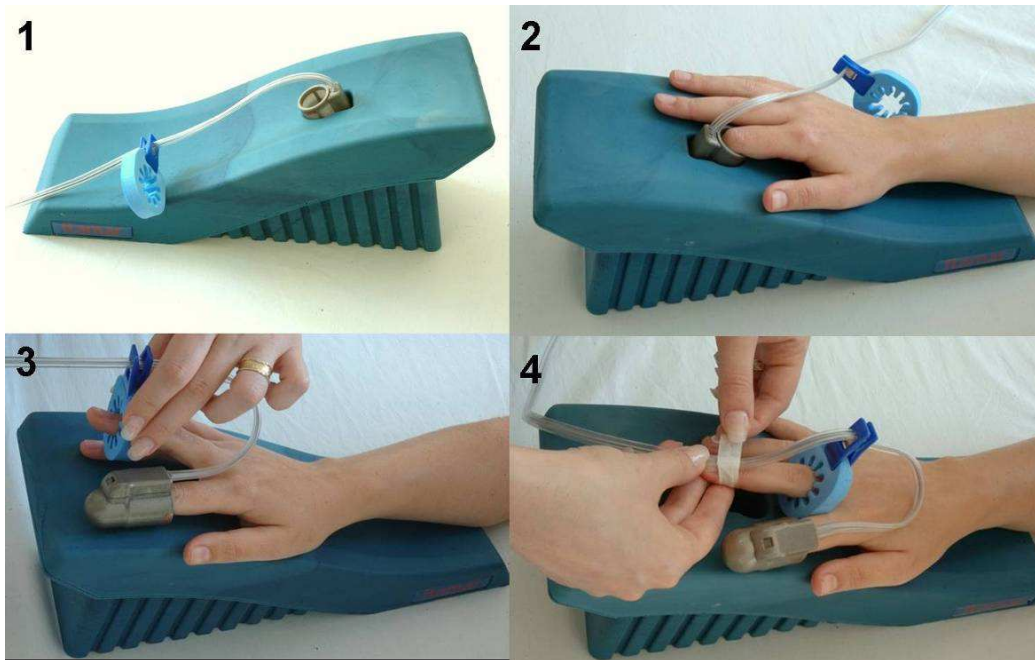
First, ensure that a blood pressure cuff is placed on the upper arm of the designated test arm. Then, the PAT probes should be placed inside the appropriate sockets of the arm-supports (see Figure 25-1). Fully deflate the probes by clicking the  icon in the software or by pressing the “Deflate” button on the device.

Place the study fingers into the probes, making sure the fingers are inserted all the way to the end of the probe (see Figure 25-2). Inflate probes by pressing the Inflate button on the device or clicking the  icon.

	<p style="text-align: center;">NOTE</p> <p>The index fingers are preferred; however any finger (other than the thumb) may be used, provided that the same finger is used in both hands.</p>
--	--

Place the blue foam anchor ring on the adjacent finger to the one with the probe on, as near as possible to the finger’s root. The anchors should be placed as far back as possible on the finger so that they do not come in contact with the PAT probe (such contact may result in mechanical artifacts during recording) – see troubleshooting guide in section 9, Table 4.

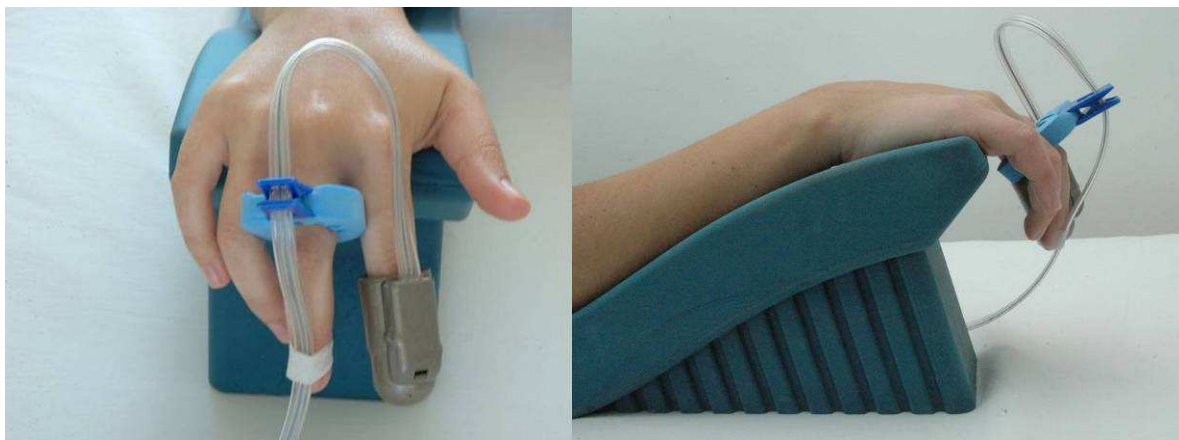
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**Figure 25 - Applying the PAT probes**

Make sure the tubing forms a loop from the probe, reaching half of the palm and back to the anchor (and attached to the anchor with the integral clip) as shown in Figure 25-3. Gently tape the tube to the tip of the anchor finger, over the finger-nail (Figure 25-4).


The patient should be instructed to refrain from moving the fingers to the extent possible.

Both patients' forearms should be supported on the arm supports (alternatively, rolled towels or bed-sheets can be used). Make sure that the probes are free and not in contact with any object (including the supporting surface), as shown in Figure 26.


**Figure 26 - Hands set-up**




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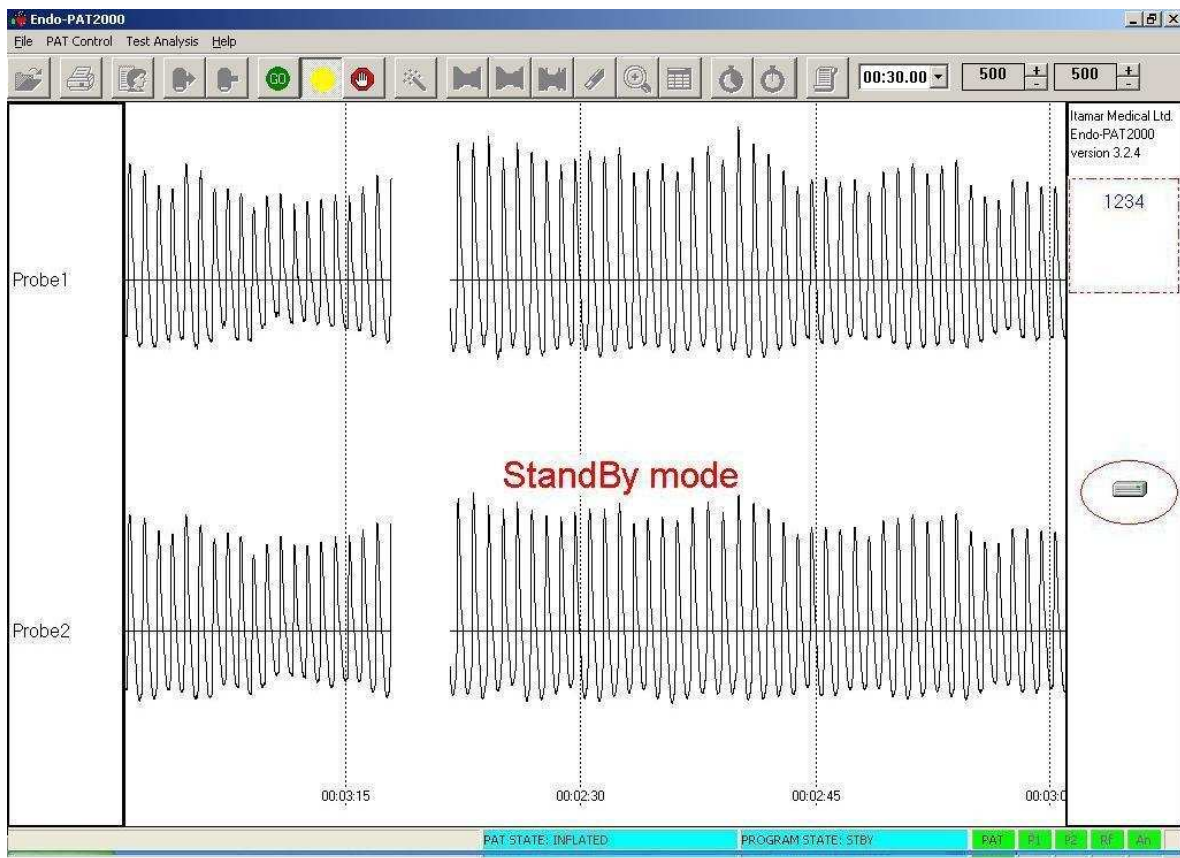
6.3 Performing the Study



	<p style="text-align: center;">NOTE</p> <p>Do not change the time or date of the computer during the study. Changing the windows time while recording might result in corrupted study.</p>
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6.3.1 Recording baseline

1. Click the Standby  icon, from the main screen. The system will display the signals from the two PAT channels, allowing the user to check the signals and adjust the signal gain/scaling to properly visualize the PAT signals without saturating the screen. It is recommended to view the signal in a 1 minute screen (00:01:00). Signals from both PAT channels (Probe 1 and Probe 2) appear in the Trace Window (as well as the trend channels, if these are selected in the system setup). Visually inspect the PAT signal (see Figure 27) for at least 1 minute. If the signal seems noisy, make sure that the probes are not in touch with anything at all. As the system equilibrates, having a few leaks in the first few minutes is normal. If you encounter more than 2-3 leaks per minute, wait in Standby mode for a few more minutes, until at least a minute passed since the last leak, or refer to the troubleshooting section (section 9).


	<p style="text-align: center;">NOTE</p> <p>If you are in the Standby mode, it is possible to stop the test, deflate & re-inflate the probes without losing the usability of the probes. Once  is pressed the probes cannot be reused after the  button is pressed.</p>
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Itamar Medical Ltd.**Figure 27 - StandBy mode**

	<p style="text-align: center;">NOTE</p> <p>While working in the StandBy mode, data is not recorded, and therefore it is impossible to review or save the study.</p> <p>The notification: “StandBy mode” (Figure 27) is displayed, and will disappear when the  button is clicked.</p>
---	---

- Click the  icon to begin study recording. Verify that the “recording” icon appears on the right hand side of the display (see the circled icon in Figure 28).

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	<p style="text-align: center;">NOTE</p> <p>Cold fingers & small fingers will have small PAT signals, with higher noise levels.</p>
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3. Initialize the stopwatch, by clicking the  icon.

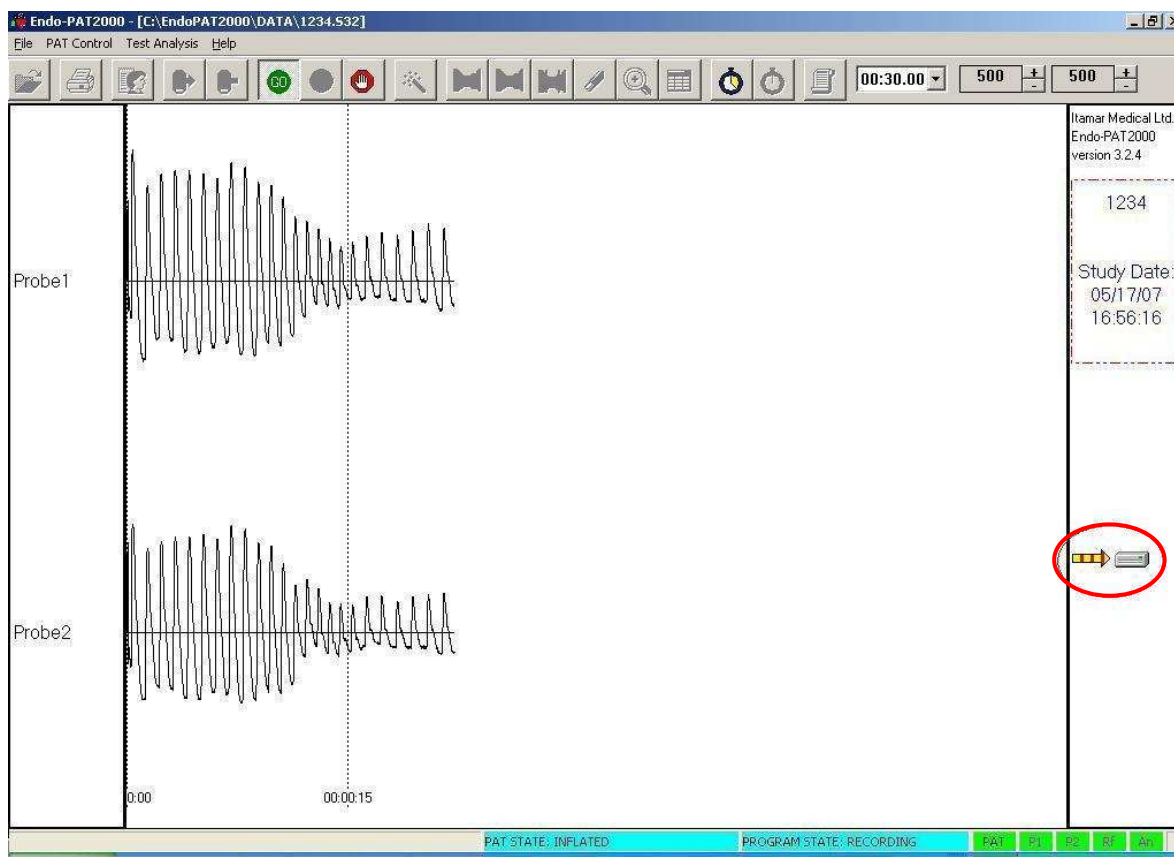



Figure 28 - Recording


	<p style="text-align: center;">NOTE</p> <p>After starting the recording the time scale will be set automatically so the full window will contain 1 minute. 15 seconds periods will be marked by dotted lines.</p>
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If the beginning of the recording is marked by patient motion artifacts or an unstable signal, consider troubleshooting procedures or extend the total period of baseline recording to give an overall period of at least 5 minutes of stable baseline data prior to the occlusion.


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6.3.2 Performing arterial occlusion

After a stable period of baseline signal recording, prepare for the occlusion:


1. Change the time scale to 15 seconds (00:00:15).
2. Amplify the signal gain of the occluded arm (either probe 1 OR probe 2) to 20,000.
3. If a stop watch will be used during the occlusion – set it for down counting from 5 minutes.
4. Explain the procedure to the patient, stressing the importance of remaining still during the test, despite the transient, strange sensations (i.e. numbness) they might feel in their arm.
5. **Rapidly** inflate the blood pressure cuff to a supra-systolic level (the recommended pressure is at least 60mmHg above systolic blood pressure and no less than 200mmHg). Verify total cessation of blood flow to the hand (total absence of PAT signal from the occluded hand). If the appearance of any PAT signal is noted, increase cuff pressure by an additional 50 mmHg and up to 300mmHg (See Figure 29).
6. Click the  icon to start the timer, when the cuff reaches the target occlusion pressure.

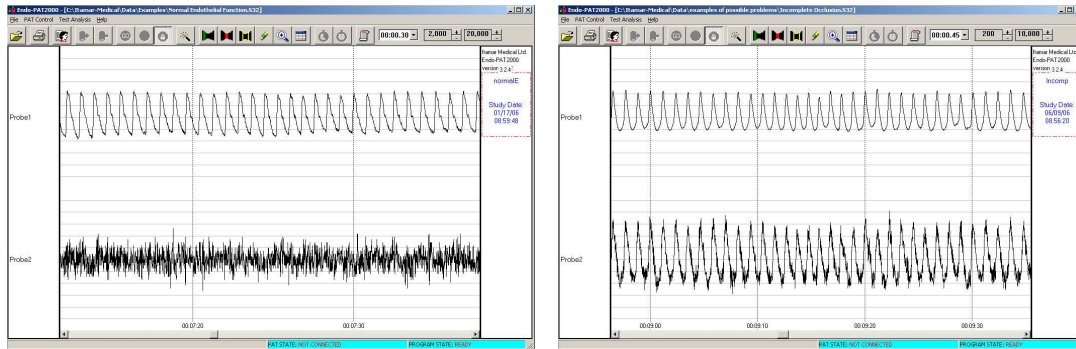
	<p style="text-align: center;">NOTE</p> <p>Without marking the beginning of the occlusion by starting the timer, you will not have any means of knowing when the occlusion period began. Thus you will not know when to release the occlusion.</p>
---	---

	<p style="text-align: center;">Warning</p> <p>Inflating the BP cuff might cause some stress and discomfort to the patient. Pay attention the patient's well-being.</p>
---	---

Maintain the arterial occlusion for exactly five minutes – periodically check the pressure in the occluding cuff to ensure proper inflation; increase pressure if required.

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	<p style="text-align: center;">NOTE</p> <p>Once the occlusion has been performed the test should not be re-started i.e. whatever problem occurs you should not stop the test and perform a new study on the same arm as vascular conditioning might have occurred. It is recommended to wait at least an hour prior to performing a new study and then to study the opposite arm.</p>
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Left – complete occlusion

Right – incomplete occlusion

In both panels the bottom signal is the occluded arm.


Figure 29 - Occlusion quality assessment


6.3.3 Post Occlusion period

1. When exactly five minutes have passed, and the stopwatch indicator starts blinking red (the occlusion is complete), completely deflate the pressure cuff **as quickly as possible**.
2. Stop the stopwatch, by clicking the  icon.
3. Click the  icon to start the timer. Continue to maintain the relaxed conditions throughout this period to ensure proper recording. The patient will experience strange sensations after the cuff deflation & might feel an urge to move the test arm. This should be discouraged.
4. When the stopwatch indicator starts blinking red (the post occlusion is complete), stop the stopwatch, by clicking the  icon.

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6.3.4 After the Study is Completed

Click the  icon to end the recording. This will also deflate automatically the probes, allowing their removal from the patient's fingers. Carefully remove the tape, PAT probes, anchors and the occluding upper arm cuff from the patient. Disconnect the PAT probes and discard them. As it is impossible to visually differentiate used from unused probes, we recommend placing a piece of tape (the one taken off the adjacent finger) around each used probe prior to discarding the probes.

Once you click the  icon to end the recording the patient file will be automatically saved to the hard disk, with the previously entered patient ID as the file name. By default, the data folder is located in the data folder, in the Itamar Medical folder in C drive.



It can also be accessed directly from the desktop by using the  icon.

After finishing recording a study, open the recorded file for review (see next chapter).

6.3.5 Setting time markers

Time markers can be inserted manually into the data while recording. This is used only for manual data analysis, as described in section 7.4.

To insert a time marker press any of the 10 number keys on the keyboard. The time marker cannot be erased after it is set. However, it does not interfere with the data. You can set as many markers as you like.

7 Review and Analysis

During a PAT study, recorded signals are viewed in the display window and, based on the appearance of the traces, a qualitative evaluation can be performed. However, subsequent review of the study using the special features described in this chapter facilitates a quantitative analysis of the acquired data.

It is recommended to review each study upon completion of its recording.

7.1 Study Data Retrieval

From the toolbar click the  icon or select Open File from the menu bar. The following dialog box appears:

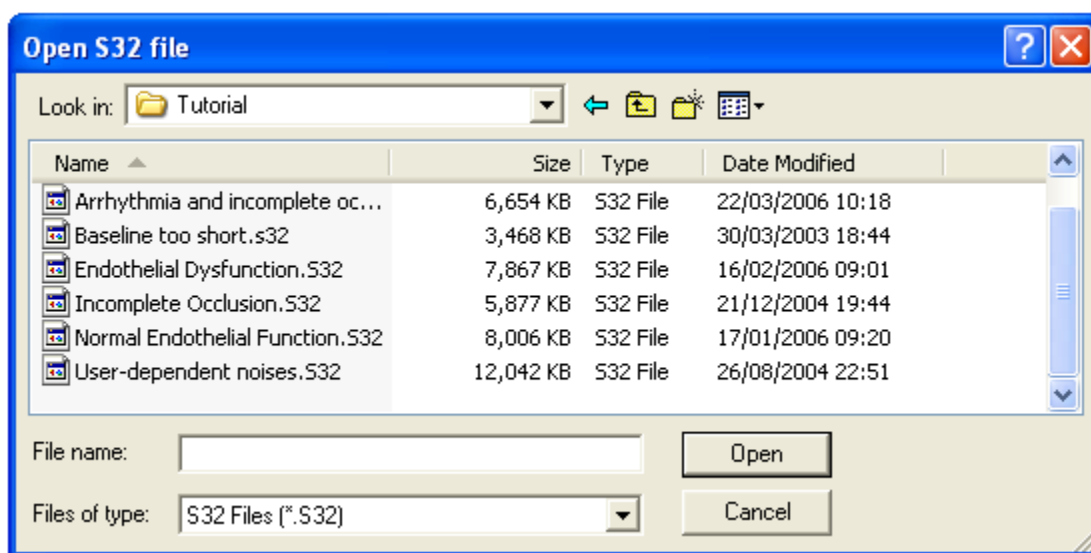


Figure 30 - Open file dialog box

Select the desired file from the list (note that the file name is the same ID number used when entering the patient's information) and click Open.

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7.2 Automatic Analysis

Click the  Icon, or select Automatic Analysis from the Test Analysis menu.

In the Endo-PAT2000 main screen, the test result's value appears in the right column as shown in Figure 31.

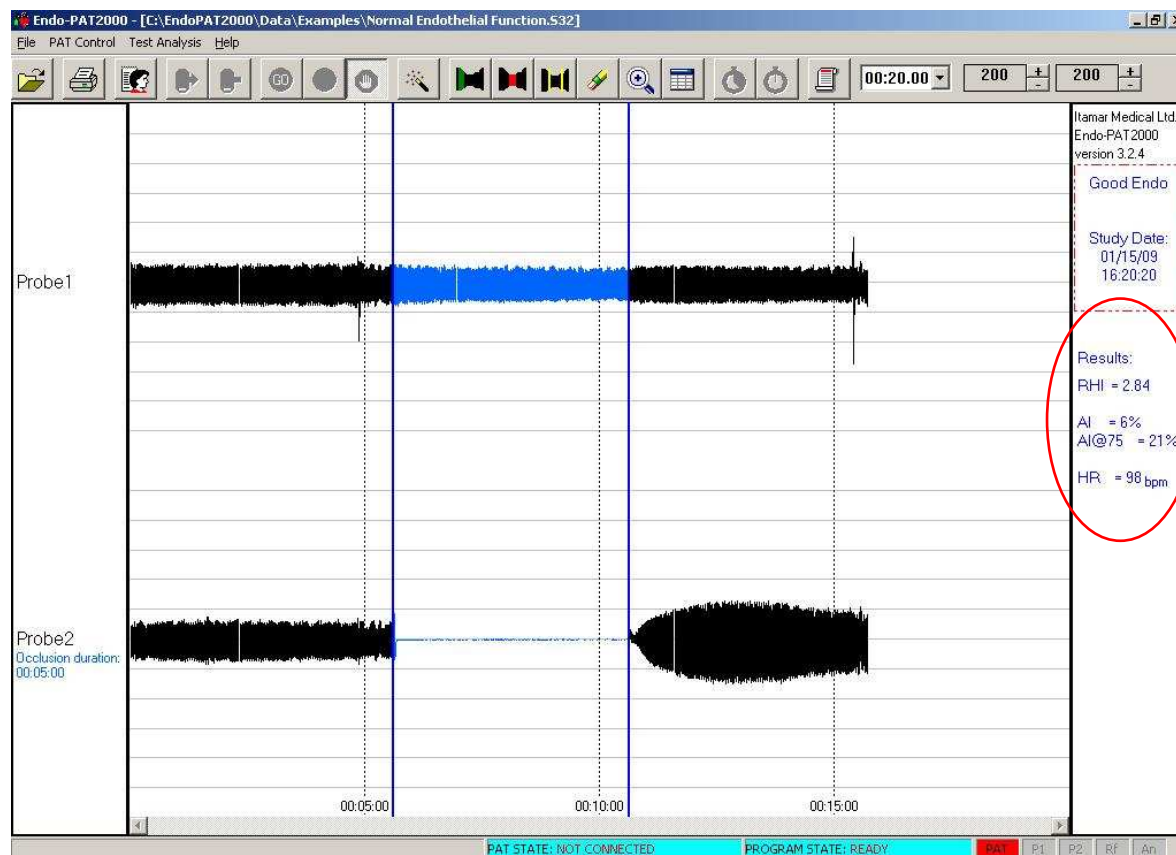




Figure 31 - Automatic analysis

	<p style="text-align: center;">NOTE</p> <p>The AI (Augmentation Index) is calculated automatically from the PAT signal in non-US and in research versions only.</p>
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The automatic analysis identifies the occlusion, and marks it in blue. Proper identification of the occlusion area is critical for the automatic analysis to correctly select the regions used in its calculations. The user should verify that the marking of the occlusion area appears reasonable. If the automatically marked occlusion area appears wrong, it can be manually selected as described in section 7.2.1.

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	<p style="text-align: center;">NOTE</p> <p>After launching the Endo-PAT2000 software, you should wait 10 seconds before running the first test analysis. This is necessary to allow termination of background processes.</p>
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The Endo-PAT2000 study results (RHI & HR) are presented on the right side of the screen (Figure 31).

The RHI (Reactive Hyperemia Index) is the post-to-pre occlusion PAT signal ratio in the occluded arm, relative to the same ratio in the control arm, corrected for baseline vascular tone of the occluded arm.

The HR (Heart Rate) is calculated from the PAT signals in the baseline region of interest.



To review the results of the study, click the  icon. The table lists relevant study parameters and results, for all analyses performed to date, with the last line in the table containing data from the most recent analysis performed.

Table 3 is a description of the information fields displayed in the table.

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a	ID
b	FileName
c	RHI: Reactive Hyperemia Index (the test result)
d	BL HR:baseline heart-rate
e	AI:Augmentation Index
f	AI@75:Augmentation Index - normelized to HR 75bpm
g	AI_N pulses:number of pulses averaged to calculate the AI
h	AI_P1
i	AI_P2
j	Warnings/Errors
k-q	Patient info: Diastolic and Systolic Pressures, Gender, Age, Height, Weight, BMI
r	%ValidBL ROI:% valid PAT signals in the Baseline region of interest
s	%Valid Post Occ ROI:% valid signals in the post-occlusion region of interest
t-w	Occlusion info – begin, end, duration and automatic/manual border detection
x-z	Baseline duration, region of interest (ROI) duration, and total study duration
aa	MeanBL o - Mean PAT signal amplitude in the baseline region of interest value, for the occluded side (suffix “o”)
ab-ao	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the occluded side (suffix “o”)
ap	MeanBL c - Mean PAT signal amplitude in the baseline region of interest value, for the control side (suffix “c”)
aq-bd	Post-occlusion signal to baseline signal ratios, at 14 consecutive 30 sec time segments, for the control side (suffix “c”)
be	RecordingTime: Date and time of test recording
bf	AnalysisTime: Date and time of test analysis
bg	RecordingVersion: The software version used for the recording
bh	AnalysisVersion: The software version used for the analysis
bi-bj	Site name & PATographer identification
bk	Comment1
bl	Comment2
bm	UserField1
bn	UserField2
bo	FRHI

Table 3 - table information(Note: fields *E* to *I* and *BO* will only appear in non-US and in research versions only)

	<p style="text-align: center;">NOTE</p> <p>Please note that the Endo-PAT analysis of Augmentation Index (AI) and FRHI are not FDA cleared and can be applied for clinical use out of the US only.</p>
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7.2.1 Manual Selection of Occlusion Borders

Click the  icon to clear all markings from previous analyses. Select the occlusion borders using one of the following 3 alternative methods:

1. Position the mouse on the occluded PAT tracing so that the curser points at the beginning of the occlusion. Click and hold down the left mouse button and drag the mouse rightwards until the curser points at the end of the occlusion area. The selected area will have inverted colors and as you mark it, the length of the selected period will be marked just below Probe1 or Probe2 on the left hand side of the screen in blue. Release the mouse button. From the “Test Analysis” menu, select the “Select Occlusion Period” option to set the manually selected occlusion area. Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.
2. Point the mouse at the beginning of the occlusion area. Right click on the mouse will open a popup menu (Figure 32). Select “Set Automatic 5 min Occlusion” from the popup menu. A five minutes segment starting at the curser position will be marked in blue. Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.
3. Point the mouse at the beginning of the occlusion. Right click to open a popup menu (Figure 32).

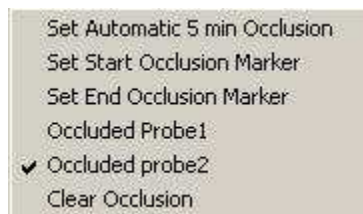





Figure 32 - Occlusion Popup Menu

Select “Set Start Occlusion Marker”. Move to the location of the end of the occlusion period, right click, select “Set End Occlusion Marker”. Occlusion markers (blue vertical lines) can be dragged to improve the fit of the occlusion area. Zoom-in to fine tune the location of the occlusion markers.

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	<p style="text-align: center;">NOTE</p> <p>It is recommended to change the time-base to a 1 minute screen (00:01:00) to make the identification of the occlusion borders easier. If the occlusion area extends beyond the edge of the window, the window will automatically scroll as you drag the mouse across its edge.</p>
---	--

- The designated occluded probe is marked on screen by the blue text: “Occlusion duration:” under the Probe label, on the left side of the screen. The occluded probe is selected automatically by the software. It can be changed by right clicking on the mouse (anywhere in the signal window) and selecting the correct occluded probe (Figure 32).
- Once the manually selected occlusion is marked, click on the  icon to run the automatic analysis using the manually selected occlusion area.
- The manual changes of the occlusion borders can be saved by selecting the “Save” option from the “File” menu. These changes will be recorded into a file with an “M32” suffix, rather than the original raw data which will have the same file name, but an “S32” suffix (for example: johnSmith.S32 & johnSmith.M32). The M32 files are 1KB in size and only contain coordinates of the occlusion borders.

	<p style="text-align: center;">NOTE</p> <p>manual changes of the occlusion borders are automatically saved</p>
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- To remove the manually added occlusion markings, right click on the mouse and select “Clear Occlusion” (Figure 32).

7.3 Batch Analysis


The Endo-PAT2000 allows the user to perform a batch automatic analysis on a group of studies as follows:


- The batch analysis command analyzes all the files located in a selected folder. If necessary, copy the files you wish to analyze to a new folder before proceeding.
- Select “Batch Analysis” From the Test Analysis menu.
- From the dialog box that opened, select the folder that contains the files you wish to analyze and click “OK”.

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- The automatic analysis will run on all the files in the selected folder. Once completed, a table will open automatically, containing all the analysis parameters (as described in Table 3) for all the analyzed files.

7.4 Manual Analysis (Research Mode only)

	<p style="text-align: center;">NOTE</p> <p>Since the manual analysis (T/B) does not incorporate certain mandatory features of the automatic analysis (e.g. contra-lateral arm correction and base line correction), it can serve for research purposes only (not necessarily endothelial dysfunction applications).</p>
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	<p style="text-align: center;">NOTE</p> <p>To enable the Manual Analysis functions, it is necessary to enable the Research Mode. Refer to section 4.4.1.</p>
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7.4.1 Marking Segments and Artifacts

Tool bar icons provide quick and easy access to the tools used to mark segments and artifacts, as well as to facilitate automatic ratio calculations between PAT traces recorded at different time segments. This feature can define any number of time intervals as artifacts, and thereby exclude them from the ratio calculations.

You can mark segments in the Trace Window, identifying two segment types (later to be used in calculations):

- B (Baseline) segment
- T (Test) segment

	<p style="text-align: center;">NOTE</p> <p>While marking segments and artifacts, errors may be corrected by clicking the  icon (“Clear all segments”). This will also erase the occlusion border markings. This tool should be used only when using the manual options described in this chapter.</p>
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To Mark a Segment

1. In the Trace Window, position the mouse pointer at the beginning of an interval to be marked.

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2. Drag the mouse horizontally along the interval—the selected segment becomes highlighted.
3. Release the mouse button at the end of the desired interval—the selected segment remains highlighted.

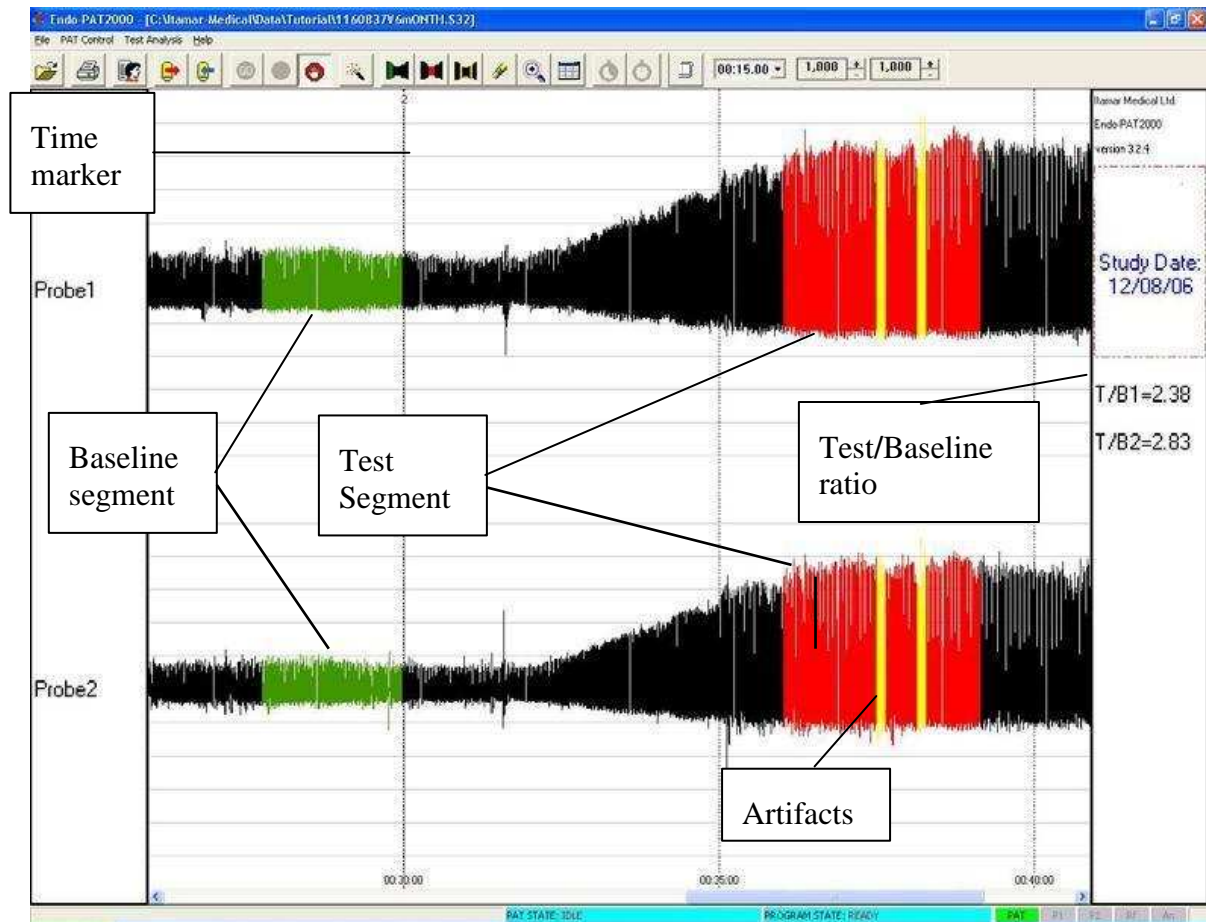






Figure 33 - Marking Segments and Artifacts

4. Set the highlighted segment to B, T or artifact, as appropriate:
 - Select a segment and click  icon to mark it as the B segment - B segment traces are highlighted in green.
 - Select a segment and click on the  icon to mark it as a T segment - T segment traces are highlighted in red.
 - Select segments suspected as artifacts and click on the  icon to mark as an artifact segment - multiple segments can be selected - artifact segment

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traces are highlighted in yellow. These segments (marked in yellow) are not used in the calculation process.

Marked segments remain highlighted in the Trace Window (Figure 33).


	<p style="text-align: center;">NOTE</p> <p>If there are noise artifacts in the region of interest in the signal, you should first mark the artifacts as explained above. Then mark the B or T segment over the marked artifacts. If you do not mark the B or T segments over the artifact markings, the artifacts will not be edited out and will be calculated in the T/B analysis.</p>
---	---


7.4.2 Analyzing PAT Ratios

After the B and T segments are marked, their PAT ratios are automatically calculated and the results displayed in the right side of the screen (Figure 33). Note that these results might be slightly different from the automated analysis, as this tool doesn't include all the analysis logic.

	<p style="text-align: center;">NOTE</p> <p>Automatically calculated segment ratios displayed in the right side of the screen (Figure 33) do not have any clinical implication. This feature is used only for research purposes and should not be regarded as device output concerning Endothelial Dysfunction.</p>
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7.5 Study report & printing

You can print the displayed data at any time during off-line review and analysis. Clicking the  icon ("Print") will send the current screen to the default printer.

To review the study report select the "View report" option in the Test Analysis pull down menu or click the  icon. The report will be exported to a picture viewer (it will take a few seconds). This report can be printed or exported to other formats (i.e. PDF).

7.6 Uploading data to the server

The software offers a quick link to the Itamar medical Uploading Service: from the Help menu, click on "Link to Itamar Medical Uploading Service". Follow the instruction in the browser to upload files.

This function requires a connection to the internet. The software will open the default browser with the correct link.

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8 Maintenance

This chapter describes preventative and regular maintenance for the Endo-PAT2000.

Only qualified medical personnel should use this equipment. In the event of equipment malfunction all repairs should be executed by qualified Itamar Medical personnel or authorized service agents.

Maintenance instructions should be followed closely to avoid unnecessary equipment failure or potential health hazards to the user or patient.

1. Inspect all cords and ensure they are not frayed or damaged. Verify that all plugs, connectors and cables are securely connected.
2. The Endo-PAT2000 device should be free of dirt and debris. Using a soft, slightly damp cloth, gently wipe the exterior of the Endo-PAT2000 device, avoiding contact with open vents and plugs.
3. The probes should be discarded after each use and replaced with new ones.

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9 Troubleshooting

	Description	Possible Cause	Action
1.	The Endo-PAT2000 does not switch on (the orange LED on the device is not on)	The Endo-PAT2000 power is switched off.	<ul style="list-style-type: none"> Switch on the Endo-PAT2000 device.
		Power cable is not plugged to the power outlet.	<ul style="list-style-type: none"> Switch off the Endo-PAT2000 device. Plug the power cable to the power outlet. Switch on the Endo-PAT2000 device.
		Power cable is not connected to the Endo-PAT2000 device.	<ul style="list-style-type: none"> Switch off the Endo-PAT2000 device. Plug the power cable to the Endo-PAT2000 device. Switch on the Endo-PAT2000 device.
2.	No communication between PC station and Endo-PAT2000 device (the green LED on the device is not lit, the Study-icon in the main screen remains dimmed or the PAT button on the bottom right of the S/W screen is red instead of green)	Endo-PAT2000 power switch is off.	<ul style="list-style-type: none"> Verify that the orange LED is on. Switch on the Endo-PAT2000 device.
		Communication cable between PC station and Endo-PAT2000 device is not connected.	<ul style="list-style-type: none"> Verify that the communication cable is connected properly.
		Another application (such as Palm Pilot Hot Sync) is assigned to the COM port.	<ul style="list-style-type: none"> Close all background applications. Verify that the COM port connected to the Endo-PAT2000 is not in use by another application.
		The communication cable is connected to the wrong COM port.	<ul style="list-style-type: none"> Plug communication cable into the other COM port. Try setting another COM port in the application.
		USB to Serial adapter not installed, or installation did not complete properly.	<ul style="list-style-type: none"> Follow instructions provided with the USB to Serial adapter to verify proper installation.
3.	Frequent pressure leaks during study	The pneumatic probe cable is not well connected to the probe or to the Endo-PAT2000 device.	<ul style="list-style-type: none"> Verify that the pneumatic probe cable is securely connected to the probe and to the Endo-PAT2000 device.
		Faulty probe.	<ul style="list-style-type: none"> Replace PAT probe.
		Faulty pneumatic cable.	<ul style="list-style-type: none"> Replace pneumatic cable.

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	Description	Possible Cause	Action
4.	Noisy signal	Something is in contact with the probes or the tubes	<ul style="list-style-type: none"> • Make sure the probes are not touched by other fingers, that they are not rested on any surface and that the tube between the probe and foam anchor is not rested on the back of the hand. • If the probe is in touch with the foam anchor on the adjacent finger you should either remove the foam anchor and trim its side on the diagonal, so it will not touch the probe or alternatively, place the foam anchor on the little finger and place a thin piece of rolled gauze as a separator between the test finger and the adjacent finger, securing it in place with some medical tape.
5.	The probes do not deflate automatically after pressing stop	Either you neglected to press “Go” (and thus still in the StandBy mode); or there is a software-hardware communication error	<ul style="list-style-type: none"> • Deflate manually by pressing the deflate button on the Endo-PAT2000 device. • If you were in Standby mode (= did not press “Go”) you should retest the patient. It is recommended to wait for an hour and switch the test arm before retesting. • If you pressed “Go” make sure the study was recorded properly by opening it for analysis.
6.	The signal looks flat and does not react to gain amplification	The relevant PAT channel is not selected	<ul style="list-style-type: none"> • Refer to section 4.4 item 6 and Figure 13

Table 4 - Troubleshooting

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The following table provides a list of system error messages that the user may encounter when attempting to run the analysis. Some of the errors may be corrected after proper manual occlusion marking (if the errors are caused by a wrong automatic detection of the occlusion borders). However, some errors have no user corrective actions that can remedy these situations. All error messages indicate that the system could not complete the analysis of the study.

Message	Explanation
Unable to open file (-n)	The system cannot open the file. The code in parenthesis (n) provides additional information for technical support (call Itamar).
Signal Length Less Than Minimum Required	The recorded signal length is less than the minimum required to run an analysis (6 min).
Signal Length More Than Maximum Allowed	The recorded signal length is more than the maximum allowed to run an analysis (150 min).
Signal is too noisy	Noisy signal prevents proper operation of the analysis module.
Allocation Problem	Internal system failure (call Itamar).
Baseline duration is shorter than minimum required	Less than 2 min and 20 sec valid baseline signals.
Occlusion Time less than minimum required	Occlusion is 90 sec or less (might be rectified after manual occlusion marking).
Occlusion Time too long	More than 10 min occlusion (might be rectified after manual occlusion marking).
Post Occlusion duration is shorter than minimum required"	Post occlusion less than 2 min and 30 sec. (might be rectified after manual occlusion marking).
Undefined occlusion	The system cannot identify the occluded section of the study (might be rectified after manual occlusion marking).
Poor Occlusion Quality	Poor occlusion quality due to too many valid pulses identified during the occlusion.
Poor Signal Quality	Poor signal quality in the post occlusion period used by the analysis (1.5 - 2.5 min post occlusion).
Program Failure	Any other problem that prevents the program to complete the analysis (call Itamar).

Table 5 - Error messages

10 Technical Information

10.1 System Requirements

- An IBM® or compatible PC Pentium/Celeron/AMD 1000 MHz CPU or higher
- Windows XP / Vista (32bit) operating system
- Any Internet browser or Excel 2000/2003
- 512 MB RAM for XP or 1GB for Vista
- 1 GB free hard disk space
- XGA display (1024 x 768 pixels) or better
- One available serial port, or one available USB port (with USB to Serial adapter installed)

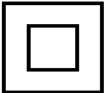


Optional Hardware

- Large removable media, such as CD-R or DVD-R for storage of study files
- Printer, higher resolution preferred. Color recommended






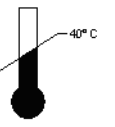

10.2 Operating System

English version Windows XP or Vista (32 bit).

10.3 Technical information about labeling

	Double isolation of power supply
	Year of manufacture
	Pay attention, first read the user manual







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	Type BF applied part
	The Endo-PAT2000 is certified by CSA
	<p>The Endo-PAT2000 complies with the CE EMC Directive and related standards.</p> <p>The unit is marked with the CE logo and a CE conformity card is included in every shipment.</p>
	Use within 2.5 years from date of manufacture
	Single use only – do not sterilize
	Maximum allowed temperature
	Name and address of the manufacturer
REF	Catalogue Number
SN	Serial Number

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10.4 Labeling

Label on the base of the Endo-PAT2000 main control unit:

Endo-PAT 2000		Type: _____	
SN _____		Rev: _____	
 Itamar Medical Ltd.		REF _____	
9 Halamish st. Caesarea Industrial Park 38900 Israel			
Tel: +972-4-6177000			
Fax: +972-4-6275598			
E-mail: support@itamar-medical.com			
			
12V DC — — — 1A		CE 0473 C 	
Made in Israel			
Must be used with software version 2.3.2 or higher			


Packaging labels:

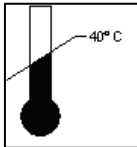


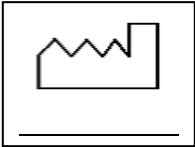
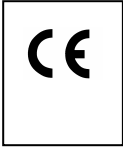
The following labels are attached to the package of the Endo-PAT2000 system:




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Endo-PAT2000 Probe Package:

**Probes for Endo-PAT**



 *Itamar Medical Ltd.*

9 Halamish, POB 3579

Caesarea Ind. Park, Israel

Tel: + 972 4 6177000

Fax: + 972 4 6275598

www.itamar-medical.com

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10.5 Specifications for Endo-PAT2000

Properties		Description
PAT Probe		Itamar's proprietary probe only
Recording Time		Limited by hard disk space, ~8MB per study of 20 minutes
Sampling Resolution		12 bit
Indications		2 LED's - power supply and communication
PAT Channel	<i>Selective Gain</i>	1 ÷ 50,000
	<i>Selectable Time Base</i>	10 sec ÷ 2 hour per screen
	<i>Bandwidth</i>	30Hz
Power Supply	<i>Input</i>	100-240 VAC 50/60 Hz
	<i>Output</i>	12V DC, 3.3A
Operating Voltage		12 V
Temperature	<i>Operation</i>	Room temperature
	<i>Storage</i>	0 - 40 °C
Humidity	<i>Operating & Storage</i>	10% - 95% (non-condensing)
Dimensions	<i>L x W x H (max)</i>	240mm x 135 mm x 185 mm
	<i>Weight</i>	3.5 kg

Table 6 - Specifications

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Appendix B: Regulatory Authorized Representative




MEDES Ltd.

P.O.Box 231
5 Beaumont Gate, Shenley Hill,
Radlett, Herts WD7 7AR.
England
Tel: +423-663-169205
Tel / Fax: +44 1923859810

Appendix C: installing the USB adaptor for Windows XP

This appendix describes how to install the MOXA adapter and driver for Windows XP Home and for Windows XP Pro editions

	<p style="text-align: center;">NOTE</p> <p>The MOXA adapter must not be connected to the computer or to the Endo-PAT2000 device while the driver is installed.</p>
---	---

1 Install the driver

- 1.1 Do not connect the USB adaptor to the computer yet.
- 1.2 Insert the “Moxa adapter drivers” CD into the CD-ROM drive.
- 1.3 Browse into CD-ROM-Drive :\XP
- 1.4 Double-click the **mxusb_setup_1.3.exe** file.
- 1.5 Complete the installation process by clicking ‘next’ on all screens, until the following screen is displayed.

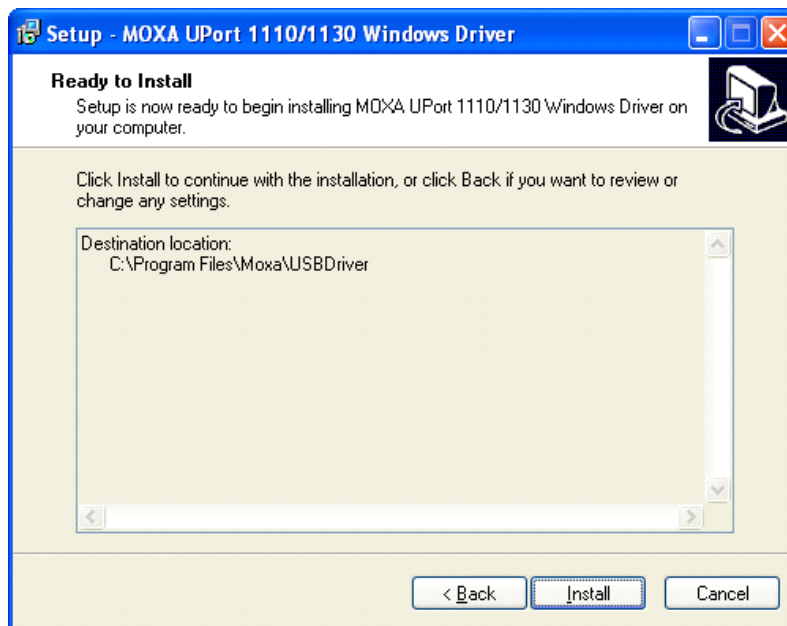


Figure 34: MOXA USB Installation – XP1

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1.6 Click “Install”.

1.7 The following screen is displayed:

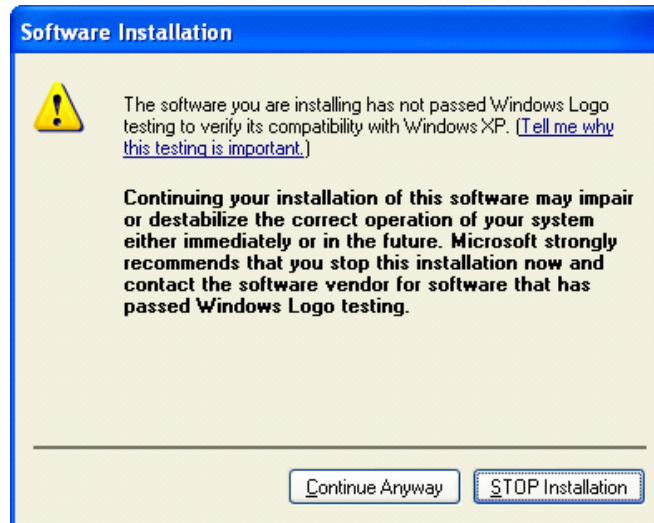


Figure 35: MOXA USB Installation – XP2

1.8 Click “Continue Anyway” (you need to approve this warning twice).
The following screen is displayed:

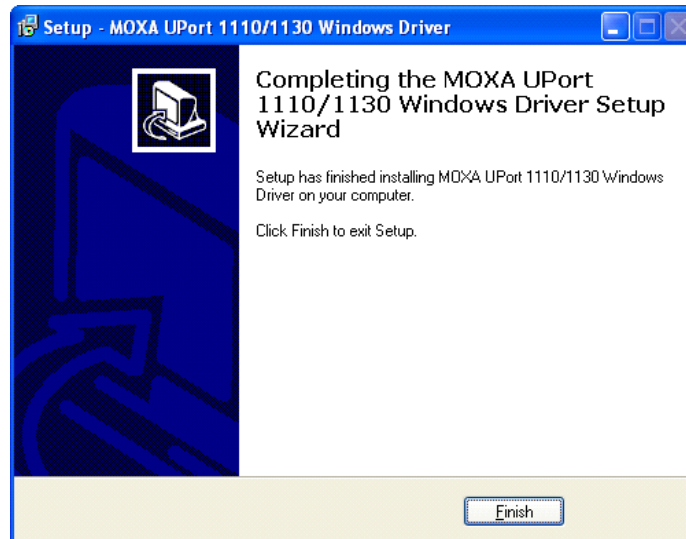


Figure 36: MOXA USB Installation – XP3

1.9 Click “Finish”.

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2. Configuring the MOXA Adapter

2.1 Plug in the adapter to your USB port.



Figure 37: MOXA Adapter

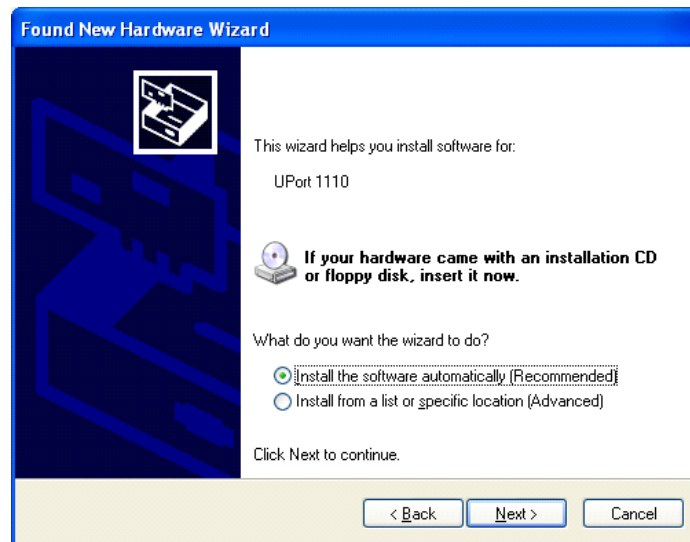
2.2 Wait for the following windows to appear.



Figure 38: MOXA Adapter Configuration – XP2

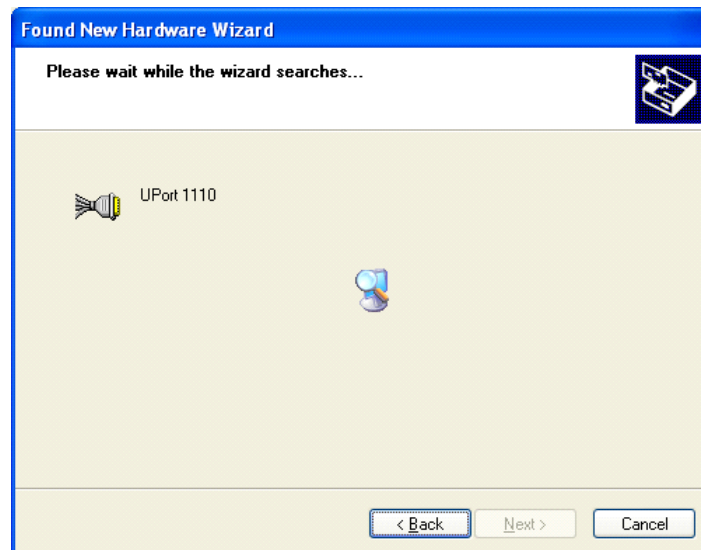
2.3 Select the “No, not this time” option, and click the “Next” button.
The following window is displayed:

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**Figure 39: MOXA Adapter Configuration – XP3**

2.4 Select the “Install the software automatically (Recommended)” option, then click the “Next” button.

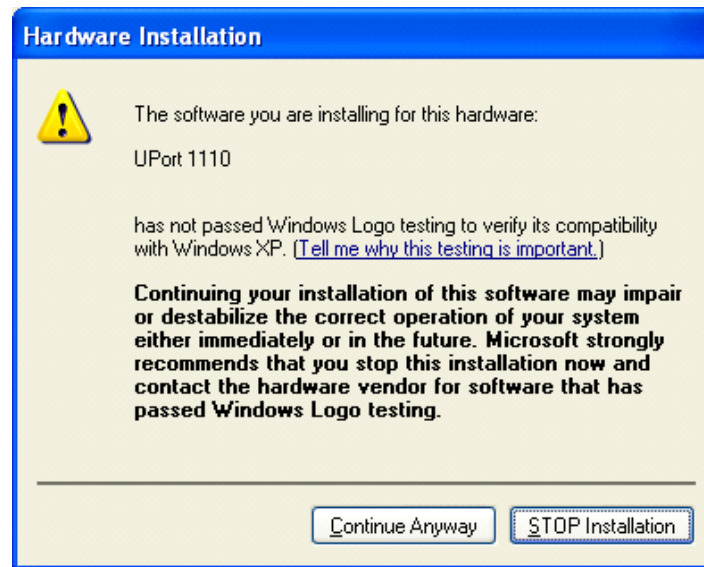
The following window appears:

**Figure 40: MOXA Adapter Configuration – XP4**

2.5 Wait for the installation wizard to find the **UPort 1110** driver; then, click the “Next” button.

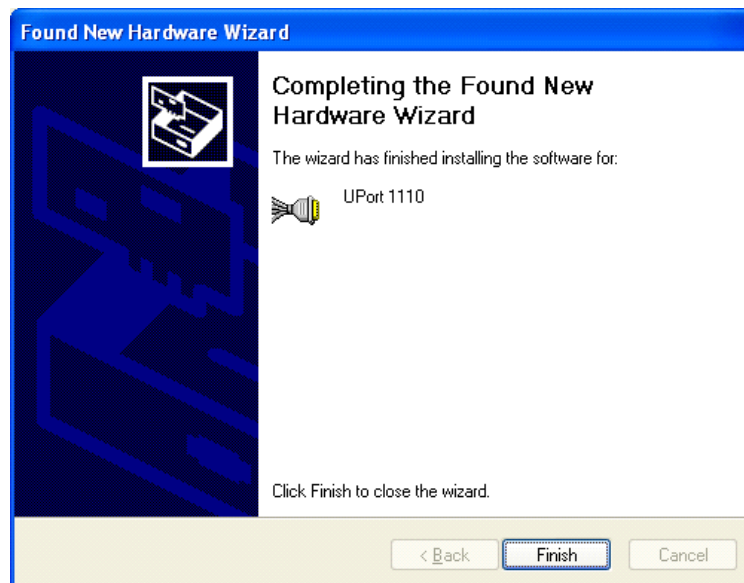
The following window is displayed:

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**Figure 41: MOXA Adapter Configuration – XP5**

2.6 Click the “Continue Anyway” button.

The following window is displayed:

**Figure 42: MOXA Adapter Configuration – XP6**

2.7 Click the “Finish” button.

2.8 Repeat steps 2-7 again when the “Welcome to the found new hardware wizard” window appears in order to install the second driver (required to complete the installation).

2.9 Move the adapter between all the USB sockets and let the system identify it.

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3. Connecting the adapter to the Endo-PAT2000

3.1 Connect the MOXA Adapter to the COM TO COM cable and tightly screw the bolts.



Figure 43- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the ENDO device and tightly screw the bolts.




Figure 44 – connect COM TO COM

3.3 Open the Endo-PAT2000 software and verify that the “PAT” indicator on the bottom right is colored green.

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Appendix D: installing the USB adapter for Windows Vista

This appendix describes how to install the MOXA adapter and driver for Windows Vista Enterprise edition

	<p style="text-align: center;">NOTE</p> <p>The MOXA adapter must not be connected to the computer or to the Endo-PAT2000 device while the driver is installed.</p>
---	---

1. Installing the MOXA driver

- 1.1 Insert the CDROM media into your CDROM drive.
- 1.2 Start the installation by double clicking on the
\ Vista\driv_win_uport1p_v1.4_build_07100420_whql file

	<p style="text-align: center;">NOTE</p> <p>If the following window is opened, please press the Allow option.</p>
--	--

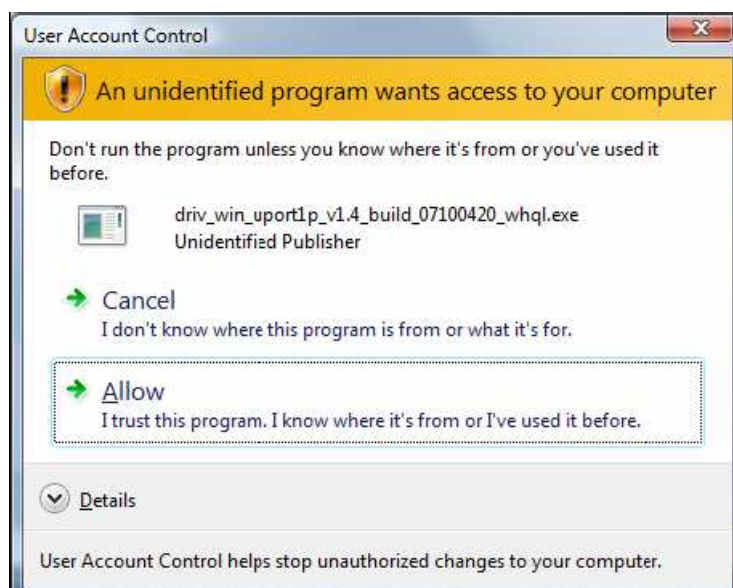


Figure 45: Windows Security Allowance

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1.3 The following window will open, press the Next Button.

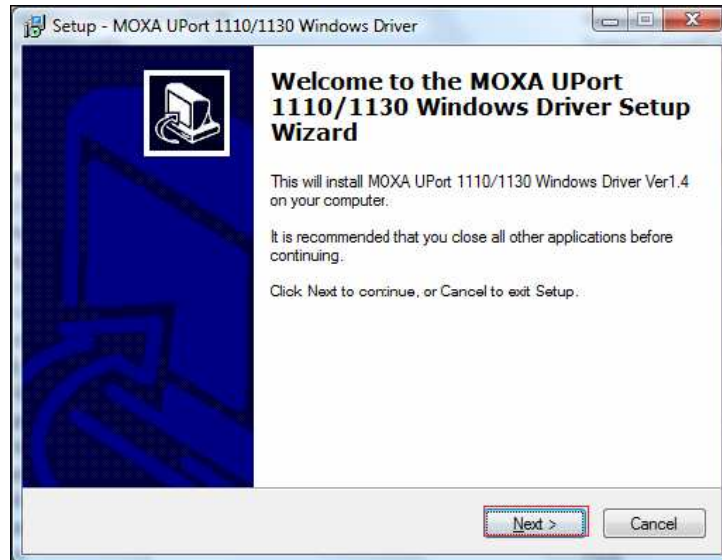


Figure 46: MOXA Uport driver installation

1.4 The following window will open, press the Next button.

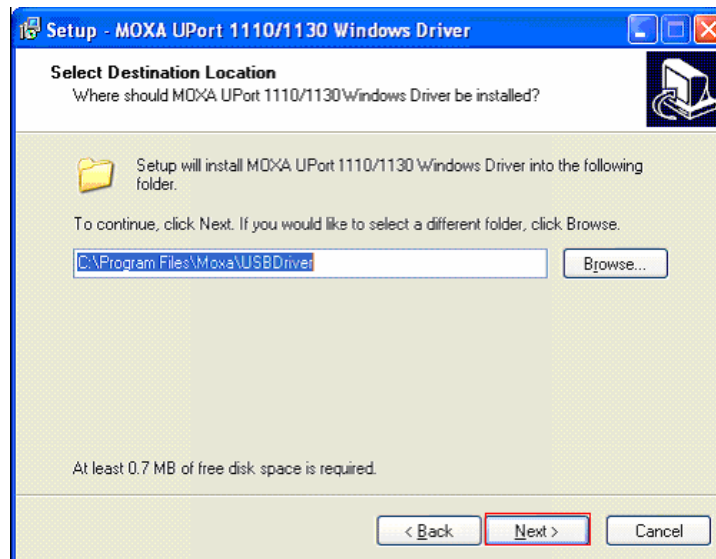


Figure 47: MOXA driver installation folder

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1.5 The following window will open, press the Install button.

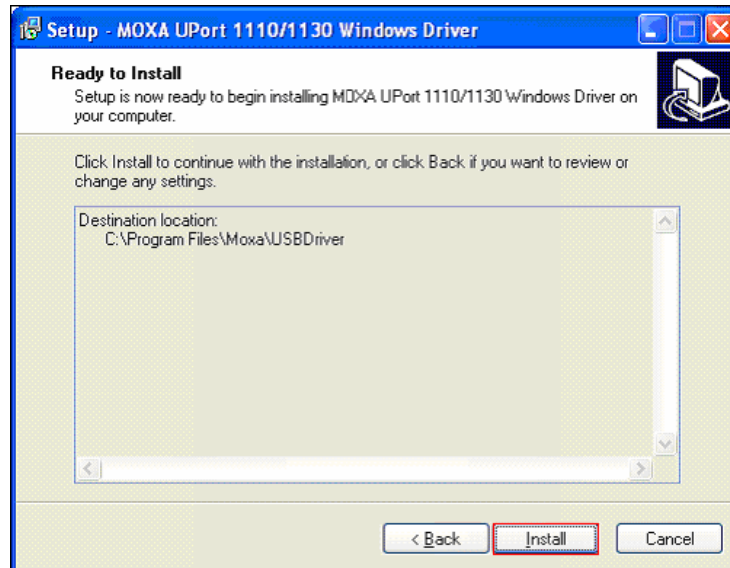


Figure 48: MOXA driver folder confirmation

1.6 Press the Finish button

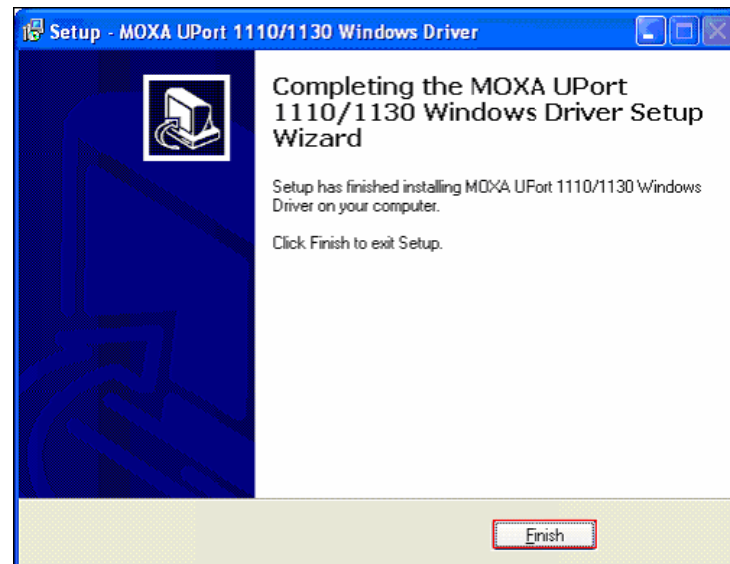


Figure 49: MOXA driver installation finish

2. Configuring the MOXA Adapter

Figure 50: The MOXA Adapter

2.3 When the installation of the driver is done the following message should appear:

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3. Connecting the adapter to the Endo-PAT2000

3.1 Connect the MOXA Adapter to the COM TO COM cable and tightly screw the bolts.



Figure 51- connect MOXA adaptor

3.2 Connect the COM TO COM cable to the ENDO device and tightly screw the bolts.



Figure 52 – connect COM TO COM

3.3 Open the Endo-PAT2000 software and verify that the “PAT” indicator on the bottom right is colored green.

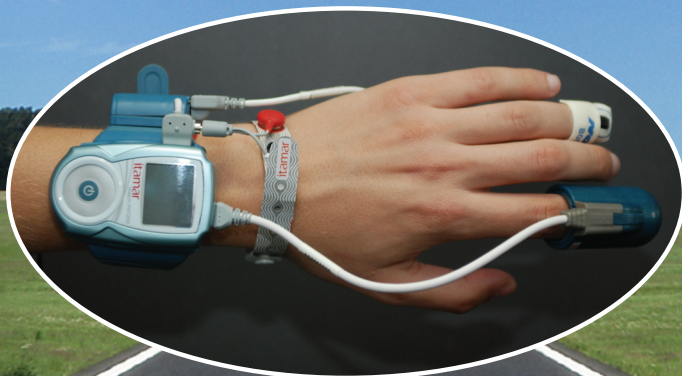
EXHIBIT 2

itamar

MEDICAL INFORMATION [IN] YOUR FINGERTIP

Sleep Testing to Go

Tamper-Proof Patient Identification



- Any night
- Any place

Only WatchPAT
offers
tamper-proof
testing

www.itamar-medical.com info@itamar-medical.com

15160

The logo for itamar, with the word "itamar" in a white, lowercase, sans-serif font on a red background.

MEDICAL INFORMATION [IN] YOUR FINGERTIP

Trucker Testing for Sleep Apnea: On-the-go

Tamper-proof Trucker Testing: Trucker testing for Obstructive Sleep Apnea is being legislated to improve road safety. Testing on traditional sleep labs is not only expensive and cumbersome but impractical for truckers never staying in one place. WatchPAT is the only device offering truckers the ability to administer the sleep test whenever convenient to them - on the road or on-the-go. Incorporating patented tamper-proof, digital bracelet, WatchPAT gives 100% positive patient identification assuming trucker safety administrators a clear Chain of Command for verifying the test results.

Importance to Trucking Concerns: We believe WatchPAT would be the ideal device to effortlessly and non-intrusively enable users, such as the Walmart trucker population, to improve health and safety outcomes on the road without sacrificing valuable work time.

The company: Itamar Medical Ltd. is a publicly-held medical device company utilizing PAT™ (Peripheral Arterial Tone) signal technology and applications. The PAT signal is a non-invasive "window" to both cardiovascular and autonomic nervous systems.

Medically acclaimed: WatchPAT is formally recognized by CMS-Medicare and has the CPT Category 1 code from the AMA. It is also reimbursed by 61% of the US private health insurance payers. It is the only ambulatory device for home testing of obstructive sleep apnea that is also authorized for reporting sleep states as well. WatchPAT was recently awarded the accolade of Top 10 Medical Innovation for 2010 by the Cleveland Clinic Kaiser Permanente of Northern California relies solely on WatchPAT to perform more than 30,000 sleep tests per year, being more economically viable than sleep labs.

REF OM2199000 Rev1

www.itamar-medical.com info@itamar-medical.com

EXHIBIT 3

itamar

Watch-PAT200

Operation Manual

Itamar Medical P/N - OM2196300



Caution: Federal (U.S.) law restricts this device to sale by, or on the order of, a physician. Not for pediatric use.

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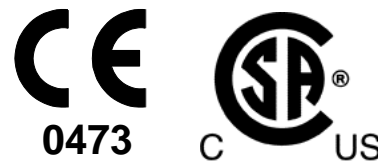
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DISCLAIMER

Itamar Medical Ltd. shall not be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of this Watch-PAT200 other than that which adheres strictly to the instructions and safety precautions contained herein and in all supplements hereto and according to the terms of the warranty provided in the License Agreement in Appendix A.

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ISO 9001:2000 and ISO 13485:2003

See appendix B for contact information of the regulatory authorized representative

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Record of Revisions

Revision	Date	Description	Chapter	Pages	Resp.
0	March 2008	Preliminary	All	All	
1	June 2008	Sleep Stages and AHI	All	All	
2	July 2008	ISO logo, list of standards, Medes address, pictures	All	All	Bonita
3	Feb 09	Updating: Itamar Medical address List of standards Labeling	-, 11 1.6 1.10.1	i, 47 3 7	Orit

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Table of Contents

1.	GENERAL INFORMATION.....	1
1.1.	Intended use / Indications for use	1
1.2.	Restrictions For Use	1
1.3.	Exclusion Criteria	2
1.4.	Data Generated by the Watch-PAT200	2
1.5.	Equipment Classification	2
1.6.	Quality Assurance System: ISO 9001	3
1.7.	CE and CSA Compliance	3
1.8.	Conventions Used in this Manual.....	4
1.9.	Safety Precautions.....	5
1.10.	Symbols used on the WP200 device labels	6
2.	OVERVIEW	8
2.1.	System Description.....	9
2.2.	WP200 Function	12
2.3.	Built-In Self-Diagnostic Procedures	12
3.	PREPARATION FOR SLEEP STUDY	18
3.1.	Charging The Battery.....	18
3.2.	Preparing The Oximetry Sensor	20
3.3.	Preparing the Wrist strap	21
3.4.	Replacing the PAT Probe	22
3.5.	Preparing the WP200 for a New Study	23
3.6.	Testing The WP200	23
3.7.	Packing The Carrying Case.....	23
4.	DATA DOWNLOAD AND ANALYSIS	24
5.	MAINTENANCE	25
5.1.	Cleaning	25
5.2.	Handling.....	26
5.3.	Replacing The Oximetry Sensor	26
5.4.	Replacing The PAT Probe Cable.....	27
5.5.	Replacing The Battery	27
5.6.	Setting The Time and Date of the WP200	28
5.7.	Storing The WP200	28
6.	APPLYING THE WP200	29

Itamar Medical Ltd.

6.1.	Preparing for use of the WP200.....	29
6.2.	Applying The WP200.....	30
6.3.	Applying The Oximetry Sensor	31
6.4.	Attaching the PAT Probe	32
6.5.	Switching On The WP200	34
6.6.	When You Wake Up	34
6.7.	Important Notes.....	35
7.	PATIENT TRAINING – GUIDELINES	36
7.1.	Walk Through The Process Of Using The WP200.....	36
7.2.	Product Introduction.....	36
7.3.	Applying The WP200.....	36
7.4.	Switching on the WP200	37
7.5.	Removing The WP200.....	37
7.6.	Patient Training.....	37
7.7.	Review Safety, General And Functional Issues	38
8.	TROUBLESHOOTING GUIDE.....	39
8.1.	Operator Error Messages	39
8.2.	Patient Error Messages	40
9.	SPECIFICATIONS	41
	APPENDIX A: LICENSE AGREEMENT.....	42
	APPENDIX B: REGULATORY REPRESENTATIVE.....	48
	APPENDIX D: DESCRIPTION OF THE WATCH-PAT PROBE	49
	APPENDIX E: MANUFACTURING DECLARATION ACCORDING TO IEC 60601-1-2.....	50

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List of Figures

Figure 1 – Packed Device	9
Figure 2 – Watch-PAT200 Device with all sensors	10
Figure 3 – The Buttons and Display	11
Figure 4 – Service Ports and Peripherals.....	11
Figure 5 – WP200 Wrist with Oximetry module	12
Figure 6 – Charging the WP200	18
Figure 7 – Oximetry Sensor.....	20
Figure 8 – Preparing The Nonin 8000JFW Oximetry Sensor	20
Figure 9 – Wrist Strap	21
Figure 10 – Disconnecting The Probe	22
Figure 11 – Probe disconnected	22
Figure 12 – WP200 Fully Prepared.....	23
Figure 13 – Replacing Oximetry Sensor.....	26
Figure 14 – Replacing the PAT probe.....	27
Figure 15 – Replacing the Battery.....	28
Figure 16 – Finger Designation.....	29
Figure 17 – Putting On The Wrist strap	30
Figure 18 – Wearing WP200	30
Figure 19 – Removing Adhesive Cover	31
Figure 20 – Positioning Oximetry On Ring Finger.....	31
Figure 21 – Fold Top Flap and Short Flap.....	32
Figure 22 – Wrap The Long Flap.....	32
Figure 23 – Flexiwrap Line Indication	32
Figure 24 – Placing Finger In PAT Probe	33
Figure 25 – Removing TOP Tab	33
Figure 26 – Removing BOTTOM Tab	33
Figure 27 – Wearing the WP200 – Ready for Sleep	33

List of Tables

Table 1 – Operator Troubleshooting.....	39
Table 2 – Patient Troubleshooting.....	40
Table 3 – WP200 Specifications.....	41

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1. GENERAL INFORMATION

This manual is part of the Watch-PAT200 (WP200) system.

1.1. Intended use / Indications for use

The Watch-PAT200 (WP200) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200 is a diagnostic aid for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). The WP200 generates a peripheral arterial tonometry ("PAT") respiratory disturbance index ("PRDI"), apnea-hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WP200's PSTAGES provides supplemental information to its PRDI/PAHI. The WP200's PSTAGES is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WP200 is not indicated for children less than 17 years old.

1.2. Restrictions For Use

- The WP200 should be used only in accordance with physician's instructions. For exclusion criteria see Section 1.3.
- Only qualified medical personnel may authorize the use of the WP200.
- Qualified medical personnel must instruct the patients how to attach and use the WP200 prior to use.
- In the event of equipment malfunction all repairs should be executed by authorized Itamar Medical Ltd. personnel or licensed service agents.
- The eligibility of a patient for a PAT study is entirely at the discretion of a physician, and is generally based upon the patient's medical status.
- The WP200 system in whole, or in part, may not be modified in any way.
- The WP200 is used as an aid for diagnostic purposes only, and should not be used for monitoring.
- Only suitably trained and qualified personnel should be authorized to prepare the WP200 equipment prior to use.
- The WP200 Operation Manual should be carefully studied by the authorized operators, and kept where it is easily accessible. Periodic review of the Manual is recommended.

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- Itamar Medical Ltd. makes no representation whatsoever, that the act of reading the Manual renders the reader qualified to operate, test or calibrate the system.
- The tracings and calculations provided by the WP200 system are intended as tools for the competent diagnostician. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.
- In the event that the system does not operate properly, or if it fails to respond to the controls in the manner described in this Manual, the operator should refer to the Troubleshooting section. If necessary, contact our service office to report the incident, and to receive further instructions.
- The step by step instructions for the patient should be carefully followed when attaching the unit to the patient.

1.3. Exclusion Criteria

The WP200 should not be used in the following cases:

- Age less than 17 years old.
- Use of one of the following medications: alpha blockers, short acting nitrates (less than 3 hours before the study).
- Permanent pacemaker.
- Sustained non-sinus cardiac arrhythmias.

1.4. Data Generated by the Watch-PAT200

The WP200 generates a PAT respiratory disturbance index (PRDI) and its derivative, the PAT Apnea-Hypopnea Index (PAHI) and PAT sleep staging identification (PSTAGES). The PRDI, PAHI and PSTAGES are estimates of conventional RDI and AHI values and REM, Deep Sleep, Light Sleep and Wake stages identification that are produced by polysomnography (PSG).

1.5. Equipment Classification

The **WP200** is a Class IIa medical device under MDD 93/42/EEC (1993) Annex IX rule 10.

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1.6. Quality Assurance System: ISO 9001

The Itamar Medical WP200 is compliant to the following standards.

	STANDARD	#
1.	Medical electrical equipment- general requirements for safety.	IEC 60601-1
2.	Medical electrical equipment electromagnetic compatibility	IEC 60601-1-2
3.	Medical Device Software- Software Life Cycle Processes	IEC 62304
4.	Quality systems – Model for quality assurance in design, development, production, installation and servicing	ISO 9001
5.	Quality systems medical devices	ISO 13485
6.	CMDR - Canadian Medical Device Regulations	SOR/98-282
7.	Risk Analysis for medical devices	ISO 14971
8.	Labeling Medical Devices	EN 980
9.	Medical Device Directive	MDD 93/42 EEC
10.	CSA standard for safety	CSA 22.2 No. 601.1
11.	UL standard for safety	UL 60601-1

1.7. CE and CSA Compliance



The WP200 complies with the CE mark according to MDD (Medical Device Directive) and related standards.




The unit is marked with the CE logo and a CE conformity card is included in every shipment.



The WP200 is certified by CSA.

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1.8. Conventions Used in this Manual

	<p>Warnings are used to identify conditions or actions, which - if the instructions are ignored - may violate patient safety, or cause damage/malfunction to the system, resulting in non recoverable loss of data.</p> <p>Les avertissements sont utilisés pour identifier les conditions ou les actions qui- si elles sont ignorées- peuvent porter atteinte à la sécurité des patients ou causer des dommages au système et résulter à une perte irréversible des données.</p>
	<p>Cautions are used to identify conditions or actions, which could cause interference with data acquisition and/or impair study results.</p> <p>Les précautions sont utilisées afin d'identifier les conditions ou les actions qui peuvent interférer avec le ramassage de données et provoquer des résultats équivoque.</p>
	<p>Notes are used to identify an explanation, or to provide additional information for purposes of clarification.</p> <p>Les notes sont utilisées pour identifier les explications et pour donner des informations supplémentaires dans le but de clarifier.</p>

1.8.1. Warnings, Cautions and Notes

The WP200 is internally powered from a 4.2 V battery.

The WP200 is portable with continuous operation.

The WP200 uses BF patient applied parts.

The WP200 uses UL listed power supply.

The power supply is used in a non-patient environment only.

The WP200 should only be transported in its original case.

There are no serviceable parts inside the WP200.

Environmental conditions during transportation & storage:

Temperature: -20°C ~ 40°C. Recommended temperature for long term storage <21°C

Relative humidity: 10% ~ 70%

Atmospheric pressure: 940 hPa ~ 1060 hPa

Environmental conditions during operation:

Temperature: 15°C ~ 30°C. Recommended temperature 18°C ~ 25°C


Relative humidity: 30% ~ 70%

Atmospheric pressure: 940 hPa ~ 1060 hPa

Sleep professionals (other than patients) using the WP200 should read the Operation Manual.






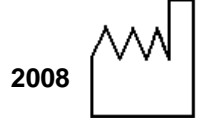


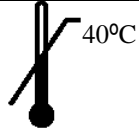

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1.9. Safety Precautions

	<p>WARNINGS</p> <p>Use only the USB charger provided (5V DC, 5W maximum capacity power supply). Only authorized personnel may charge the WP200. Failure to heed this warning may cause permanent damage to the equipment.</p> <p>Do not let the unit get wet.</p> <p>Avoid placing food or water on any part of the system.</p> <p>In the event of fire use only fire extinguishers approved for use on electrical fires.</p> <p>Handle unit with care. This unit is sensitive to extreme movements and to falling.</p> <p>Do not attempt to connect or disconnect any part of the unit.</p> <p>Do not try to introduce any foreign object into the unit.</p> <p>The WP200 MUST be charged ONLY after being removed from the patient!</p> <p>The WP200 MUST be removed from the patient BEFORE connecting it to a PC!</p> <p>The Adult Flex Pulse Oximetry Sensor may cause skin sensitivity to the patient. Discontinue use of the NONIN double-backed adhesive tape strips or the Hydrogel tape strips if the patient exhibits allergic reactions to the adhesive material.</p> <p>AVERTISSEMENTS</p> <p>Utiliser seulement un 5V DC, 5W alimentation d'énergie. Seul les techniciens autorisés peuvent charger la montre PAT. Ignorer cet avertissement peut causer des dommages irréparables à l'équipement. Ne pas mouiller l'unité. L'unité est sensible au mouvement extrême et à la chute. L'utiliser avec précaution. Ne pas essayer de brancher ou débrancher une des parties de l'unité.</p> <p>Ne pas introduire un objet étranger à l'intérieur de l'unité.</p> <p>Le système WP200 doit être rechargé uniquement après avoir été retiré de la main du patient.</p> <p>Il est impératif de retirer le système WP200 de la main du patient avant de le relier à l'ordinateur pour faire fonctionner les programmes.</p> <p>L'Oximètre pur adulte "Flex Pulse" peut produire des sensibilités dermatologique aux patients.</p>
---	---

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1.10. Symbols used on the WP200 device labels

	Consult operating instructions
	Consult accompanying documents
	BF Type Applied Parts
	The WP200 is certified by CSA
	The WP200 complies with the CE EMC Directives and related standards
	Year of manufacture
	Battery Operating Voltage
	Do not re-use
	Temperature limitation
	Use by

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1.10.1. WP200 labels



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2. OVERVIEW

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep, along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of OSAS in the adult population.

The WP200 is worn on the wrist and is utilizing a plethysmographic based finger-mounted probe, to measure the PAT (Peripheral Arterial Tone) signal. The PAT signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT signal amplitude. The PAT signal is recorded continuously and stored on an embedded micro SD card, together with data from a built-in pulse-oximetry sensor (mounted on an adjacent finger) and an actigraph (embedded in the WP200). Following the sleep study, the recordings are automatically downloaded and analyzed in an offline procedure using the proprietary zzzPAT software.

The zzzPAT algorithms use the four WP200 channels (PAT, oxygen saturation, pulse rate and actigraphy) for the detection of respiratory events, differentiation between wakefulness and sleep stages such as Deep, Light and REM sleep. The software issues comprehensive reports of the study, with statistics and graphic presentation of the results. The whole night data can be viewed and the automatically detected events can be revised manually.

An optional sensor for Snoring and Body Position provides snoring in decibels during sleep and 5 body positions (right, left, prone, supine and sit).

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2.1. System Description

The WP200 system is comprised of the following items:

- WP200 device that includes:
 - Embedded actigraph
 - Embedded pulse oximeter
 - Embedded CPU and electrical circuit card
 - Embedded micro SD card drive
 - Rechargeable Lithium Ion Battery
 - LCD display
- PAT probe
- PAT probe connection cable
- Pulse oximeter sensor – with single use adhesive pads
- Wrist Strap
- Snore and Body Position sensor - optional
- USB battery charger
- USB cable
- Step-by-Step Reference Guide
- Carrying case

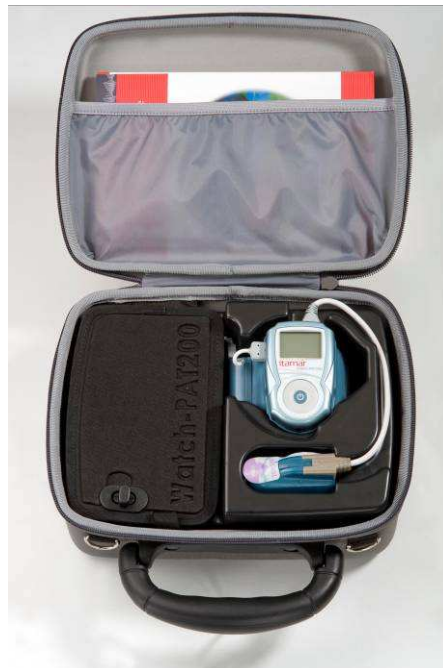


Figure 1 – Packed Device

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Figure 2 – Watch-PAT200 Device with all sensors

An additional item required for the operation of the system is the zzzPAT kit. zzzPAT is a proprietary PC software for initializing the study, retrieving, analyzing and displaying the data. For more information, refer to the zzzPAT Operation Manual.

2.1.1. User Interaction with the WP200

Keys

The WP200 has the following keys (see Figure 3):

- Central On/Enter key to power on the WP200 (the only key visible to the patient)
- Outer ring containing four keys (left, right, up, down) that may be used by the Operator for entering the diagnostic mode and navigating through the diagnostic menu. These keys are hidden from the patient.

LCD display

The display is used for reading status and error messages. The display is divided to three sections: Title, Info and Status.

- Title: Current operational mode and time
 - PATIENT mode while recording night study
 - DIAGNOSTIC mode while testing device
 - PC HOST while connecting to PC
 - CHARGER mode while connecting to USB Charger
- Info: Specific information depending on operational mode

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- Status: Message indicating device status depending on operational mode



Figure 3 – The Buttons and Display



Figure 4 – Service Ports and Peripherals

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Figure 5 – WP200 Wrist with Oximetry module

2.2. WP200 Function

The WP200 records the following channels:

- PAT Signal
- Oxygen saturation
- Actigraphy (movement)

The overnight sleep study data is stored on an embedded micro SD card in the WP200. After the study is recorded, the data is downloaded from the WP200 through the USB cable using the zzzPAT software. The zzzPAT software, utilizing automatic algorithms, detects respiratory and other events that occurred during sleep as well as periods of REM, deep sleep, light sleep and wakefulness. The pulse rate signal is derived from the PAT signal and used in the automatic analysis. The software issues comprehensive detailed reports of the study. The whole night data can be viewed on the PC screen and the automatically detected events can be revised manually.

2.3. Built-In Self-Diagnostic Procedures

2.3.1. Operator tests

The WP200 contains a comprehensive built-in self-diagnostic procedure. This procedure is available to the operator and hidden from the patient. The procedure can be accessed if the UP and DOWN keys (see Figure 3) are pressed simultaneously after the device is powered ON (during the first 30 seconds only after the device is powered ON). The procedure performs the following tests:

- Device Test – tests the WP200 for errors before performing a night study (make sure all probes are connected before initiating this test)

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- Oximetry Sensor Test – verifies oximetry sensor is connected and shows average saturation

The Device test is the default test. Once the device test has passed you should also run the oximetry sensor test.



Note

In all times, the current time is shown in the upper right hand corner of the LCD display.

To run the self-diagnostic procedure:

- Press the ENTER button (Center key) for 2 seconds till the Itamar medical logo appears on the LCD screen
- Immediately press the **UP + DOWN** keys (see Figure 3) simultaneously for 1 second

The following screen will be displayed:

```
DIAGNOSTIC      22:40
2.2140          20-Jul-08
*device test (30001)
  oxi test
  end testing
Select test ↑↓
```

- First line displays title and current time
- Second line displays current embedded S/W version (2.2139) and current date
- Third line displays option for running device test (serial number of device in parenthesis)
- Fourth line displays option for running oximetry sensor test
- Fifth line indicates option for end testing (turn device off). If no test is selected within 3 minutes the WP200 device will automatically shut down
- The Up, Down keys (↑↓) navigate between the lines.
- An asterisk will indicate current selection. When moving the ↑↓ keys, the asterisk will move to indicate the current selection. Press the central Enter key to make the desired selection.

It is recommended that you perform the device and oxi test every time you prepare the WP200 for a night study.

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2.3.2. Device test

At the completion of the device test, a **TEST PASSED** indicates that the device is ready for the night study.

DEVICE TEST	22:50
ID=111-11-1111	
sbp=missing	
<-Back	
TEST PASSED	2:54

At the completion of the device test, a **TEST FAILED** indicates a problem that should be taken care of before the device is released for a night study.

DEVICE TEST	22:50
ID=111-11-1111	
oxi=mod missing	
pat=missing	
<-Back	More->
TEST FAILED	2:54

The following are the possible error/warning messages:

- File error: not loaded, missing – the study file was not loaded or somehow the file was deleted
- Battery error: low – needs charging
- Probe error: used, missing, bad – connect an unused probe
- Oximetry error: module missing - connect oximetry module
- Hardware (H/W) error: error code - contact customer support
- SBP (Snore and Body Position sensor) warning: sensor missing – does not affect PASSED status
- RTC (Real Time Clock) warning: faulty – indicates problem with internal clock but does not affect PASSED status

More-> indicates that there are more error/warning messages and will be displayed if the Right (->) button is pressed.

<-Back we move to previous screen.

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2.3.3. Oximetry test

For the oximetry test make sure the sensor is attached to the finger. At the end of the test the saturation and/or any error message will be displayed:

```
OXI TEST          22:50
SaO2=98%

Attach to finger
<-Back
Testing...
```

```
OXI TEST          22:50
SaO2=N/A
oxi=mod missing
Attach to finger
<-Back
Testing...
```

The possible oximetry error messages are:

- Oximetry error: module or sensor missing - connect oximetry module and sensor.
- SaO2= Not Available (N/A) - attach sensor to finger.

The blood saturation is continuously updated, therefore wait for one minute or so for the saturation to stabilize when testing.

<-Back we move to previous screen.

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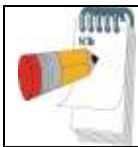
2.3.4. Patient test

When the patient turns on the WP200 by pushing the On/Enter key (center button) for about 2 seconds a self-diagnostic test is automatically performed and the following screen is displayed:

PATIENT	22:51
Please wait	
Testing...	

If the WP200 passes this self-diagnostic test, the following screen will be displayed

PATIENT	22:51
GOOD NIGHT!!!	
Time elapsed=9:50	
Recording...	



Note

During recording the LCD display turns off to conserve battery life. Any key pressed during Recording will turn on the LCD for 30 seconds.

If the WP200 fails this self-diagnostic test, the following screen will be displayed:

PATIENT	22:51
Error=xxxx	
Device S/N=xxxxxx	
Call Help Desk	
TEST ABORTED	

- The error message will be displayed for 1 minute then the WP200 will shut off.

The following are the possible error/warning messages:

xxx1 - battery low

xxx2 – Nonin module/sensor disconnected

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xx2x – PAT probe error (used probe)

xx4x – File error (no new file)

xx8x - PAT probe error (bad probe)

x4xx - SBP (Snore and Body Position sensor) missing warning

**Note**


The "x" stands for 0-F value (Hexadecimal code)

Error codes are additive, i.e. both PAT probe and File errors will produce error code xx6x.

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3. PREPARATION FOR SLEEP STUDY

3.1. Charging The Battery

	<p style="text-align: center;">Warning</p> <p>For AC charging use only a USB charger having a 5V DC output, with 5W minimum capacity. Using any other charger may cause permanent damage to the WP200 and may jeopardize the operator.</p>
---	---

The battery must be charged every time the WP200 is prepared for use. The battery may be charged through the USB port of a computer, or with the USB charger provided.

To charge the WP200:

1. Disconnect the Oximetry module by disconnecting the Oximetry module connector.
2. Gently slide the WP200 out of the wrist strap until a click is heard and the USB port is exposed. Be careful not to damage the oximetry module connector and cable.
3. Connect the USB port of the WP200 to the USB port of a computer using the USB cable provided or to the USB charger provided (see Figure 6).



Figure 6 – Charging the WP200

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4. The LCD will blink slowly and the following screen will be displayed:

CHARGER	22:51
Bat=3.12 V	
Charging...	

- The display will show “**CHARGER**” if you are charging with the USB charger or “**PC HOST**” if you are charging with a computer.
 - The current battery voltage is shown.
 - Charge the battery the first time for approximately three hours. Thereafter recharging takes approximately 1-1.5 hours.
5. When charging is complete, the LCD will stop blinking and the following screen will be displayed:

CHARGER	22:51
Bat=4.2 V	
Charging complete	

6. Disconnect the charger or communication cable. The WP200 will switch off in 30 seconds.
7. Reseat the WP200 in the wrist strap by gently sliding it back in until a click is heard.
8. Check that the oximetry module connector is properly connected to the WP200.

Should a charging error arise the LCD will blink rapidly and the following screen will be displayed.

CHARGER	22:51
Bat=4.2 V	
Charger fault	

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3.2. Preparing The Oximetry Sensor

Use Nonin 8000JFW Flexiwrap pad and Nonin oximeter as supplied.



Figure 7 – Oximetry Sensor

1. If the sensor was previously used, carefully remove the used Flexiwrap pad from the sensor. Remove any remaining adhesive from the sensor – if necessary clean the sensor using isopropyl alcohol.
2. Place the new Flexiwrap pad with the printed side facing down on a flat surface.
3. Partially peel off the paper covering of the pad to expose the adhesive area around the two cut out sections.
4. Place the sensor on the pad with the back facing the sticky side placing the sensor's protrusions into the corresponding cutout sections as shown in Figure 8.
5. Reapply the paper covering of the pad.

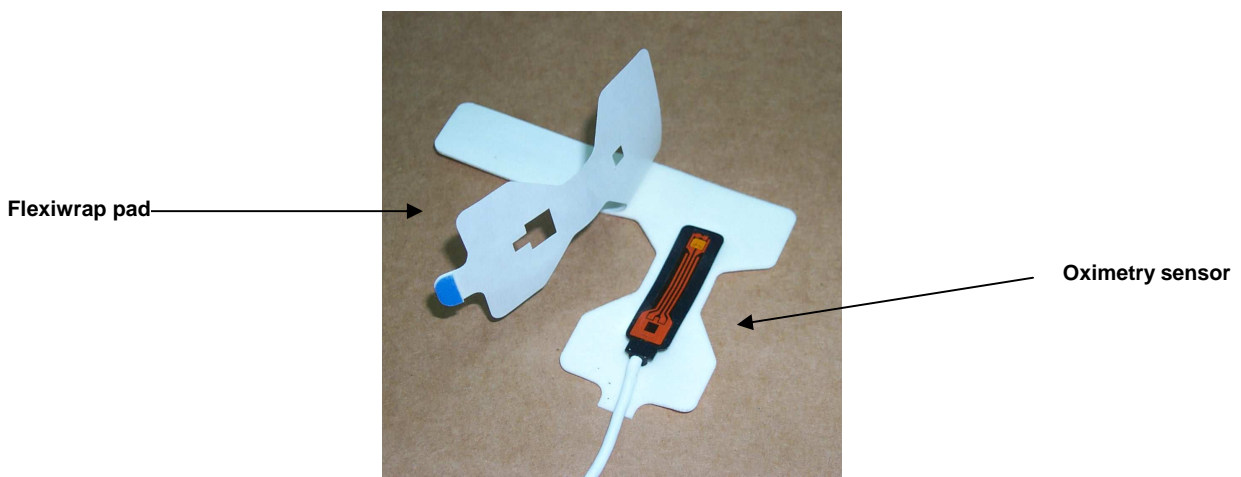


Figure 8 – Preparing The Nonin 8000JFW Oximetry Sensor

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3.3. Preparing the Wrist strap

The wrist strap requires no special preparation other than ensuring its cleanliness. You may clean it if needed. Take care not to allow the oximetry module or connector to get wet (see Figure 5). See section 5.1 for detailed cleaning instructions.

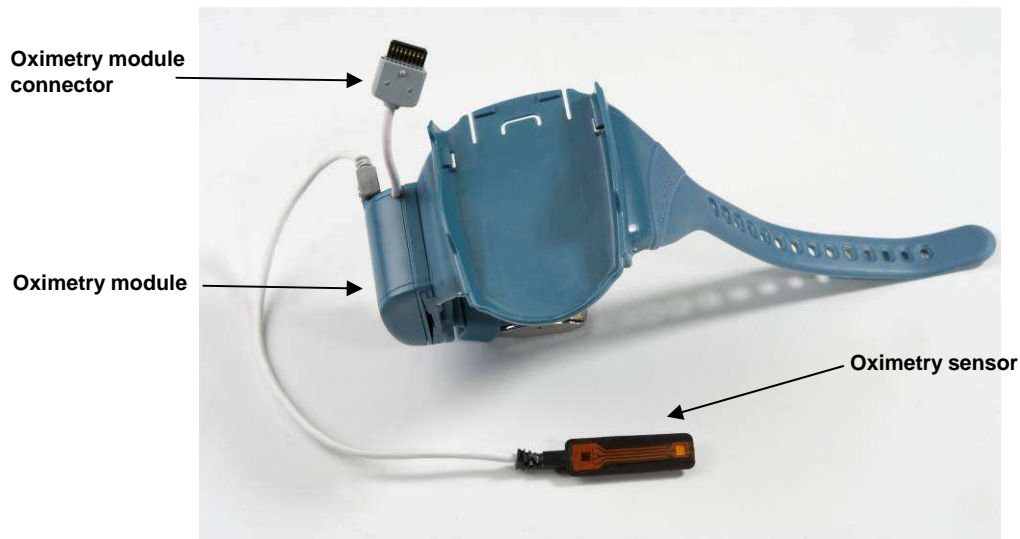


Figure 9 – Wrist Strap

3.3.1. Mounting the WP200 on the wrist strap

To mount the WP200 on the wrist strap:

1. Gently slide the WP200 into the wrist strap until a click is heard indicating that it is properly seated.
2. Connect the oximetry module connector (Figure 9) to the oximetry module port on the WP200 (Figure 4).

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3.4.Replacing the PAT Probe



Warning

The PAT probe connector is very sensitive and therefore should never be left exposed. **Keep the connector connected to the probe at all times, especially during cleaning.** Replace the probe just before performing the Device test.

Remove a used probe by pressing the blue tab (clip) marked by the arrow in Figure 10, and then, holding the gray slider, gently slide it away from the probe – do not pull the slider off by pulling the cord, as it may damage the wiring. Properly dispose of used probes.



Figure 10 – Disconnecting The Probe

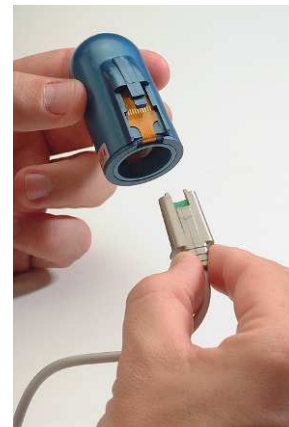


Figure 11 – Probe disconnected

Connect a new probe by inserting the gray slider to the probe until the blue tab of the probe clicks into its place.



Note

Take care when inserting the gray slider to insure proper seating in the probe.

The WP200 is now ready for performance of a sleep study by the patient. (Figure 12)

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Figure 12 – WP200 Fully Prepared

3.5. Preparing the WP200 for a New Study

Refer to the zzzPAT Software Manual for preparation of the WP200 for a new study.

3.6. Testing The WP200

Run the built-in self-diagnostic facility as described in Section 2.3 above

3.6.1. WP200 self-diagnostic test results and trouble-shooting

Should any of the self-diagnostic tests fail or report error messages refer to the trouble-shooting guide in Section 8.

3.7. Packing The Carrying Case

The following items must be placed inside the carrying case, in their respective compartments:

- The WP200 mounted in the Wrist strap with the PAT probe and oximetry sensor attached.
- Body Position and Snore sensor (optional)
- Step-by-Step Reference Guide to the WP200.



Note

Demonstrating the use of the WP200 to the patient is important for obtaining reliable recordings and improving patient confidence.

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4. DATA DOWNLOAD AND ANALYSIS

Following the sleep study the WP200 is returned to the referring sleep clinic for data downloading and analysis by the zzzPAT software.

To download and analyze the study data:

1. Connect the USB port of the WP200 to the computer (see Figure 4)
The WP200 will switch off and then switch on in charging mode.
2. Activate the zzzPAT software to download and analyze the study data.

See the zzzPAT Software User Manual for detailed instructions.

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5. MAINTENANCE

The WP200 has been designed and manufactured to meet all safety requirements applicable to medical equipment. To ensure maximum safety of operation, the system should be used and maintained in strict compliance with the safety precautions, warnings and operating instructions provided in this Manual.

The system contains no user-serviceable parts. It should be maintained and serviced only by qualified service personnel, authorized by Itamar Medical Ltd.

5.1. Cleaning

The various components of the WP200 have different cleaning requirements.

- The WP200
- The wrist strap
- The oximetry sensor

5.1.1. Cleaning the WP200

There is no need to clean the unit during ordinary operation. Should it become necessary to clean the WP200, proceed as follows:

1. Wipe parts with a clean, dry, lint-free cloth.
2. Clean casing with lint free cloth lightly moistened with 70% alcohol.



Warning

Clean the WP200 only with the PAT probe attached.

5.1.2. Cleaning the oximetry sensor

The Nonin 8000JFW pulse oximetry sensor has two parts, the single-use adhesive band and the optical sensor with cable and plug. The sensor/cable component is reusable, and should be cleaned as described in section 3.2.

5.1.3. Cleaning the Wrist Strap

You may clean the wrist strap with lint free cloth lightly moistened with 70% alcohol.

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5.1.4. The PAT probe

The PAT probe is designed for a single use only. It may not be cleaned and must be discarded and replaced before each study.

5.2. Handling

Handle with care:

- Use only the designated case for transportation
- Store at room temperature, and avoid direct sun light
- Do not expose the WP200 to extreme temperature or humidity conditions (such as storing in a car or bathroom)

5.3. Replacing The Oximetry Sensor

Should it become necessary to replace the oximetry sensor, proceed as follows:

1. Carefully disconnect the oximetry sensor from the oximetry module on the wrist strap.
2. Carefully insert the connector of the new oximetry sensor cable to the oximetry sensor port in the oximetry module on the wrist strap (see Figure 13) noting proper alignment (3 round protrusions facing up).



Figure 13 – Replacing Oximetry Sensor

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5.4. Replacing The PAT Probe Cable


To replace the PAT probe cable:

1. Carefully disconnect the PAT probe cable from the WP200.
2. Connect a new PAT probe cable by gently inserting the connector into the WP200, noting proper alignment (3 round protrusions facing up).



Figure 14 – Replacing the PAT probe

5.5. Replacing The Battery

	<p style="text-align: center;">Warning</p> <p>Replace the battery only with an authorized battery provided by Itamar Medical Ltd.</p>
---	--

In the event of a battery error message during the self-diagnostic tests or after charging, it may be necessary to replace the battery.

To replace the battery:

1. Open the battery compartment cover with a Phillips screwdriver.
2. Remove the battery.

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3. Gently remove the connector from the connection port.
4. Insert the connector of the new battery into the port. It will slide in easily. Don't force the connector into the port. It may properly be inserted in only one direction.
5. Place the battery and connecting wire into the battery compartment.
6. Close the battery compartment cover and secure with the Phillips screwdriver.



Figure 15 – Replacing the Battery

5.6. Setting The Time and Date of the WP200

The WP200's Time and Date can be set through the zzzPAT application. Refer to the zzzPAT Software Manual for preparation of the WP200 for a new study.

5.7. Storing The WP200

- The WP200 should be stored in its carrying case at room temperature and low humidity.
- In order to preserve battery performance when the WP200 is not in use, store with the battery fully discharged. Before storing the WP200 allow it to deplete the battery charge until it shuts down automatically.

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6. APPLYING THE WP200



Note

These instructions are designed to help the patient use the WP200 **after** seeing a demonstration by trained personnel of how to mount the probes on his/her fingers and correctly operate the WP200.

The following detailed instructions are summarized in the patient's step-by-step reference guide. They are written as if the reader is the patient using the WP200.

6.1. Preparing for use of the WP200

Before using the WP200, review the following notes:

- Remove all rings, watches and jewelry from your non-dominant hand and wrist.
- The probes may be worn on any two fingers of your non-dominant hand. We recommend that the oximetry sensor and PAT probe be attached to the ring and index fingers respectively (Figure 16). The following instructions relate specifically to these fingers. Patients with very large fingers may use their small finger (pinky) for the PAT Probe.
- Ensure that fingernails of fingers that will be monitored are well trimmed, (less than 1mm from nail bed) with no jagged edges. Clip and file nails, if necessary
- Remove artificial fingernails or dark nail polish from the monitored fingers

You may need some assistance putting on the WP200. If needed have someone present to assist you.

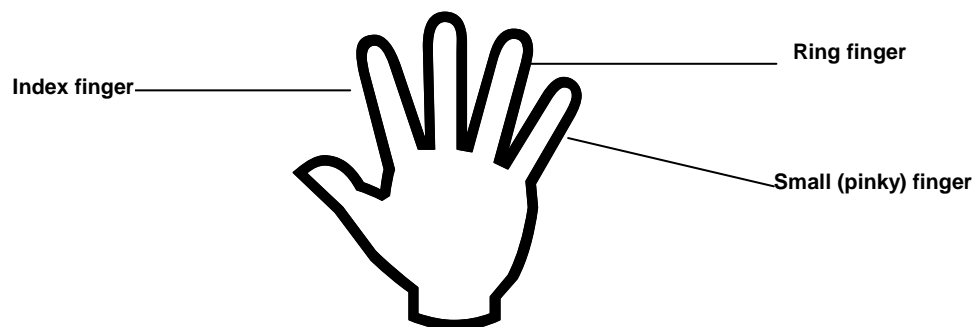


Figure 16 – Finger Designation

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6.2. Applying The WP200

To apply the WP200 to your wrist:

1. Open the carrying case and take out the wrist strap with the WP200 mounted. All parts should already be connected, as illustrated in Figure 12.
2. Ensure that the WP200 is firmly seated in the wrist strap. If not, gently seat the WP200 in the strap by sliding it into its seating position. You will hear a click when the WP200 is properly seated in the strap.
3. Place the wrist strap with the WP200 on the non-dominant arm and close it snugly but not tightly. Ensure that the rounded end is towards the body and the open end towards the fingers. You may find it convenient to place the wrist strap with the WP200 face down on the table and then place the back of the wrist over the wrist strap in order to fasten the straps (Figure 17).
4. At this point both probes are hanging loose (Figure 18).



Figure 17 – Putting On The Wrist strap



Figure 18 – Wearing WP200

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6.3. Applying The Oximetry Sensor

Now you will attach the oximetry sensor to your ring finger, as was demonstrated to you and is illustrated in the figures below.

6.3.1 Applying the Nonin 8000JFW Oximetry Sensor

If you are using the Nonin 8000JFW oximetry sensor proceed as follows:

1. Remove the adhesive strip from the unit (see Figure 19)
2. Position the oximetry sensor on your ring finger with the wire on the bottom side of the finger (see Figure 20) – the finger should reach the centerline marker on the pad
3. Fold the bottom short flaps around your finger (see Figure 20)
4. Fold top flap over the finger and fold the short flap around your finger (see Figure 21)
5. Complete this procedure by wrapping the long flap around the short wrapped flaps (see Figure 22).
6. Ensure that the dotted line of the Flexiwrap pad is properly located, as indicated by the arrow (see Figure 23), and that the two square black protrusions are opposite one another.
7. The oximetry sensor is now attached. When the WP200 is turned on, the sensor will glow red.

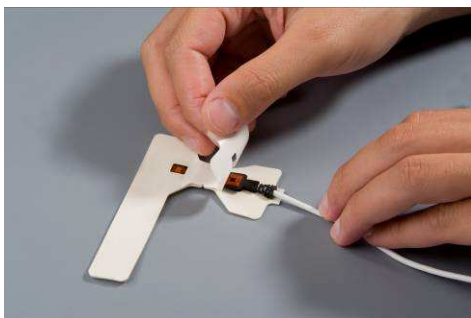


Figure 19 – Removing Adhesive Cover



Figure 20 – Positioning Oximetry On Ring Finger

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Figure 21 – Fold Top Flap and Short Flap



Figure 22 – Wrap The Long Flap

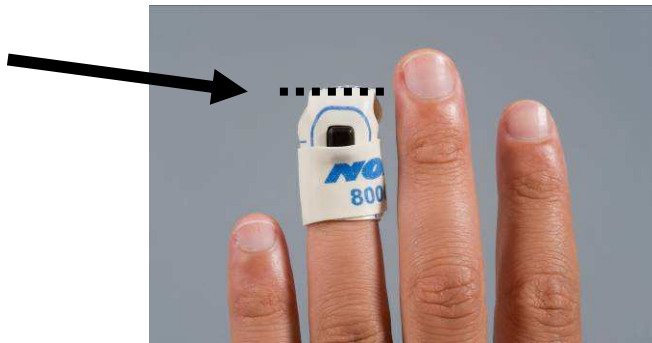


Figure 23 – Flexiwrap Line Indication

6.4. Attaching the PAT Probe

Proper probe placement is critical for good performance.



Note

The tabs inside the probe should be removed only **AFTER** the finger is inserted into the probe.

To attach the PAT probe:

1. Insert your index finger (or other if so instructed) gently into the probe until it reaches the end (see Figure 24).
2. Make sure that the paper tab marked TOP is above your nail and the tab marked BOTTOM is below your finger.
3. Detach and pull the tab marked TOP slowly and firmly towards the back of your hand, until completely removed from the probe (Figure 25).

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4. Detach and pull on the tab marked **BOTTOM** slowly and firmly towards the back of your hand, until completely removed (Figure 26). You might feel a slight suction once the tabs are removed.

The PAT probe is now attached (Figure 27).



Figure 24 – Placing Finger In PAT Probe



Figure 25 – Removing TOP Tab

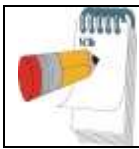


Figure 26 – Removing BOTTOM Tab



Figure 27 – Wearing the WP200 – Ready for Sleep

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Note

DO NOT remove the PAT probe before the night study is terminated. Once the probe is removed it cannot be re-attached.

6.5. Switching On The WP200

You are now ready to switch on the WP200.

Just before you lie down to go to sleep, firmly press the ON/Enter center button (Figure 3) until the LCD display lights up. After a short delay the LCD will display “Good Night! Recording...”

PATIENT	22:51
GOOD NIGHT!!!	
Time elapsed=9:50	
Recording...	



Note

To conserve the battery the LCD display will switch off after a few seconds. Pressing any button will restore the display for about 30 seconds.

6.6. When You Wake Up

When you awake, remove the WP200 from your arm as follows:

1. Remove both probes from your fingers.
2. Take off the wrist strap.
3. Place all parts in the carrying case.



Note

Pressing the center button does not switch off the WP200. The oximetry sensor red light will remain lit. Approximately ten hours after the WP200 is turned on, it will switch off. This is normal.

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6.7. Important Notes

Wearing the WP200 should not cause any discomfort or pain. If you experience wrist or arm discomfort, loosen up the wrist strap. If the discomfort is not alleviated immediately, call the service number.

- Do not attempt to connect or disconnect any part of the unit.
- Do not try to introduce any foreign object into the unit.
- Do not try to connect the unit to an electrical supply or any other unit, machine or computer.
- If any part appears disconnected or does not resemble the illustrations, call the service number for assistance.
- Do not, under any circumstances, attempt to fix the problem yourself.

If you have any questions about using the machine, before, during or after your at-home recording session, call the service number.

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7. PATIENT TRAINING – GUIDELINES

7.1.Walk Through The Process Of Using The WP200

- Product introduction – WP200, wrist strap, PAT probe, oximetry sensor
- WP200 and wrist strap attachment
- Probe and sensor attachment
- Switch on
- Ending the study

7.2.Product Introduction

- Open the Demo-case and introduce the ‘Quick guide step-by-step’ instruction manual.
- Introduce each component by its name and identify it as in the figures in the manual.

7.3.Applying The WP200

Use the Demo Kit.

- Demonstrate how to apply the WP200 on your wrist while following the ‘step by step’ guidelines and referring to the relevant figures.
- Demonstrate the following:

1. Hand Preparation

- Remove rings, watches and jewelry from hand
- Remove fingernail polish and artificial nails
- Make sure finger nails are closely trimmed

2. Wearing the Wrist Strap

- Should be comfortable, not too tight

3. Attaching the WP200

- Make sure the WP200 is properly mounted on the wrist strap. If it is loose, gently slide it in until you hear a click.

4. Attaching the oximetry sensor

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- Before PAT probe attachment
- If using the Nonin 8000FJW sensor, demonstrate proper placement of the finger on the Flexiwrap pad – note the position of the fold line, and that the two black square protrusions are opposite each other.
- Folding the flaps of the Flexiwrap pad to secure sensor properly.
- Make sure it is not too tight

5. Attaching the PAT probe

- Insert finger all of the way into the probe
- Remove the Tabs one by one by pulling slowly and gradually
- Both tabs must be fully removed
- The probe is limited to a SINGLE USE. Do not remove probe during the night.

7.4. Switching on the WP200

Demonstrate switching on the WP200 by pressing the round center button

- Push button firmly until the LCD display lights up
- The oximetry sensor light will glow red during the entire test

7.5. Removing The WP200

- Demonstrate how to remove the WP200 and place it back in the carrying case.
- The oximetry sensor light will keep glowing red.
- The WP200 doesn't switch off – once turned on it will record until the battery is exhausted.

7.6. Patient Training

Following your demonstration have the patient attach the demo device by himself.

Verify that the attachment is properly done. Especially monitor carefully attachment of the oximetry sensor.

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7.7. Review Safety, General And Functional Issues

- Avoid exposing the WP200 to extreme conditions (high temperature, high humidity)
- Provide a telephone number to call in case of questions or problems.

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8. TROUBLESHOOTING GUIDE**8.1. Operator Error Messages**

If an error message is displayed while performing the self-diagnostic tests, take the actions specified below. If the problem persists contact Itamar or an authorized representative.

Table 1 – Operator Troubleshooting

Error	Possible Reason	Action
File error		
Loaded		
Unloaded	File not loaded	Load file
Battery error % full	Battery defective or uncharged	Charge battery or replace
Probe error		
Used	Probe previously used	Replace probe
Missing	Probe absent	Attach probe
Oximetry sensor error		
No sensor	Sensor absent	Replace sensor
Disconnected	Sensor disconnected	Connect sensor cable to port
No communication	Module not connected	Check cable connection
Hardware status error code	WP200 defective	Consult Itamar or authorized representative
SBP discon	WP200 defective	Consult Itamar or authorized representative
RTC faulty	WP200 defective	Consult Itamar or authorized representative
Short recording time	Patient removed the WP200 or probe from hand prematurely	Explain proper use to patient
	Insufficient battery charge caused early termination of recording	Recharge battery and try again
	Damaged WP200	Contact your authorized sales representative

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8.2 Patient Error Messages

If an error message is displayed when the patient powers on the WP200, the patient should take the actions specified below. If the problem persists the patient may contact Itamar or an authorized representative directly.

Table 2 – Patient Troubleshooting

Error	Possible Reason	Action
Oximetry sensor light turns off while WP200 is on.	Oximetry sensor plug not fully inserted	Verify that oximetry sensor plug is fully inserted into the WP200
	Faulty oximetry sensor	Check the oximetry sensor probe for damage and replace if necessary
Oximetry sensor disconnected	Sensor not properly connected or faulty	Check connection. If problem persists replace sensor
WP200 doesn't switch on	ON button not activated	Press the ON button firmly for at least 3 seconds
	PAT probe not connected	Ensure probe is connected and try again
Probe disconnected	Probe may not be connected, or may be a used probe	Check connection of probe to cable and cable to the WP200; check if probe has been previously used and replace with new probe if necessary
Hardware code	WP200 failure	Contact Itamar or authorized representative

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9. SPECIFICATIONS**Table 3 – WP200 Specifications**

Properties		Description
PAT Probe		Itamar's proprietary probe only
Recording Time		10 hours (minimum)
Oximetry Probe		Custom Nonin 8000J Flex Sensor
Channels		Measuring 4 signals: PAT, Pulse rate, Oximetry, Actigraphy
Sample Resolution		PAT and Actigraph – 12 bit; oximetry – 1%
User Interface		LCD display
Accuracy	<i>Pulse rate</i> <i>Amplitude</i> <i>Oximetry</i>	30-150 \pm 1 bpm 0-1V 1% 70-100% \pm 1%
PAT Channel	<i>Fixed Gain</i>	600
	<i>Fixed Offset</i>	1.5 Volts
	<i>Bandwidth</i>	0.1-10 Hz
Data Storage	<i>Media</i>	Micro SD card
	<i>Capacity</i>	64 MB (minimum)
	<i>Format type</i>	Formatted to FAT 32
Power Supply	<i>Battery</i>	Proprietary, rechargeable Lithium Ion Battery
	<i>Capacity</i>	> 500-700 mAh
	<i>Cell Type</i>	Lithium Ion cell type
	<i>Internal Charger</i>	Proprietary Lithium Ion battery charger
	<i>External Power Supply</i>	5V DC, 5W with USB connector
Operating Voltage		3.3 V
Temperature	<i>Operation</i>	Room temperature
	<i>Storage</i>	0 – 50 °C
Humidity	<i>Operating & Storage</i>	10% – 60% (non-condensing)
Dimensions	<i>L x W x H</i>	80 x 50 x 20 mm
	<i>Weight</i>	0.13 kg

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APPENDIX D: DESCRIPTION OF THE WATCH-PAT PROBE

The Watch-PAT probe is an opto-pneumatic finger-mounted probe.

Its role is to continuously measure the relative state of the vasomotor activity in the distal part of the finger based on a plethysmographic method. The Watch-PAT probe is designed to cover the distal part of the finger with a uniform pressure field extending to the tip of the finger. This design prevents venous blood pooling, engorgement and stasis, which inhibits retrograde venous shock wave propagation, and allows partial unloading of arterial wall tension that significantly improves the dynamic range of the measured signal. The optic component of the probe measures the optical density related changes of the arterial blood volume in the digital arteries, associated with each heartbeat. Peripheral arterial constrictions, when present, are shown by attenuation in the PAT signal amplitude, a marker of sympathetic activation.

The Watch-PAT probe is an integral part of the Watch-PAT device.

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APPENDIX E: MANUFACTURING DECLARATION ACCORDING TO IEC 60601-1-2

Manufacturer Declaration According to IEC 60601-1-2

Electromagnetic Emissions

The Model Watch-Pat 200 (WP-200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Watch-Pat 200 (WP-200) should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11: 2004 + A2: 2006	Group 1	The Model Watch-Pat 200 (WP-200) uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11: 2004 + A2: 2006	Class B	The Model Watch-Pat 200 (WP-200) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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Manufacturer Declaration According to IEC 60601-1-2

Electromagnetic Immunity

The Model Watch-Pat 200 (WP-200) is intended for use in the electromagnetic environment specified below. The customer or the user of the Watch-Pat 200 (WP-200) should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Watch-Pat-200 (WP-200), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio (AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Watch-Pat 200 (WP-200) is used exceeds the applicable RF compliance level above, the Watch-Pat 200 (WP-200) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Watch-Pat 200 (WP-200).</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

EXHIBIT 4

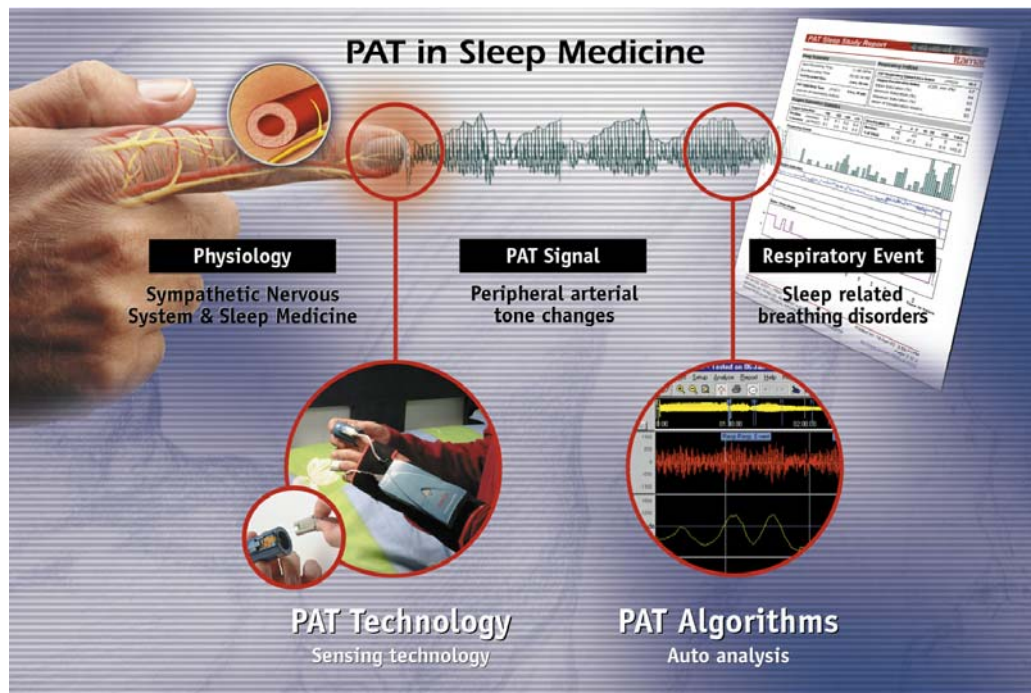
itamar

zzzPAT

For Watch-PAT100 & Watch-PAT200

Software Operation Manual

Itamar Medical Cat. No. OM2197432



Caution: Federal (U.S.) law restricts this device to sale by, or on the order of a physician.

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Software Version: 4.2.58

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Revision: Base 3-0

Revision	Date	Description	Chapter	Pages
Base- 0-0	December 2000	Preliminary	All	All
Base-1-0	May 2001	1	All	All
1-2	October 2001	Build 032	All	All
1-3	December 2001	Update	4, App. A, B	15, 64
1-4	April 2002	Build 035	All	All
1-5	January 2003	Rev. 2.0	All	All
Base-2-0	November 2003	Addition of workgroup functionality Revised chapter order Added Index Combined to cover both versions 1.5 and 2.4	All	All
Base- 3-0	March 2004	Addition of AHI Single Icon application Addition of file transferring option Time Range and Sleep Indices report User and General Settings Export to CSV	All	All
Base- 4-0	February 2005	Version 3.0 <ul style="list-style-type: none"> • Improved REM Analysis • Database Wizard functions are integrated within zzzPAT (under "Tools" menu) • Direct Export of Studies to CD-Writer (Win XP only) • Patient ID can be edited • Option to open Sleep report automatically after "Load from Flash" or "Open Study" • Toolbar improvement • Removed need for WP100 Device clock setting • Removed Win 98 support 		All
Base- 5-0	November 2006	Version 4.0 <ul style="list-style-type: none"> • Added support for Snoring and Body position sensor • Added 3rd optional page to Sleep report • New options at General Settings/Report Appearance for 1, 2 or 3 page report • Events report shows Resp.Events (RDI), Resp.Events (AHI) and 		All

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		<p>desaturations only</p> <ul style="list-style-type: none"> • File>New Study Details: Removed all mandatory requirements except Patient ID • A backup of the database for every day of the week will be automatically performed behind the scenes • Automatic printout of labels (1 or 2 labels as configured) while the Compact Flash is initialized with patient data • “Follow up” report will show reviewed and reported studies • Patient's weight and height appear in Sleep report • Enable manual addition/deletion of Respiratory events • Export for Interpretation services option • The valid sleep time used for the calculation of the respiratory indices appears in the second page of the report 		
Base- 6-0	June 2008	<p>Version 4.2.56</p> <ul style="list-style-type: none"> • Report changes • Support of MS-SQL server • New Study – new patient fields • Follow Up Report changes • Light/Deep Sleep stages 	All	All
Base- 7-0	August 2008	<p>Version 4.2.57 WP200 support</p>	All	All
Base- 8-0	August 2009	<p>Version 4.2.58 WP200 Patient Identification Bracelet support Multiple nights study</p>	All	All

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Table of Contents

1	INTRODUCTION TO THE ZZZPAT	1
1.1	Intended Use of the Watch-PAT100 & Watch-PAT200.....	1
1.2	The zzzPAT S/W – Definition	1
1.3	Overview	1
2	INSTALLATION	3
2.1	Overall Description of zzzPAT Software	3
2.2	Hardware Requirements	3
2.3	Installation of the Compact Flash drive	4
2.4	Installing zzzPAT software	5
2.5	Step by step installation instructions	6
2.6	Upgrading from previous versions	15
2.7	Defining the USB drive.....	16
2.8	Opening an ftp reception account with Itamar Support.	17
2.9	Before using zzzPAT Software for the first time	17
3	SETTING UP ZZZPAT CONFIGURATION	21
3.1	Setup>Set USB Drive.....	21
3.2	Setup>Directories	21
3.3	Setup>User Settings.....	21
3.4	Setup>General Settings	25
4	USING ZZZPAT	37
4.1	Preparing a New Study	37
4.2	Managing Patient Studies	47
4.3	The Display Screen	51

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4.4	Signal Display Options	56
4.5	Review, Analysis and Report Study	59
4.6	Reports.....	63
5	EXPORTING DATA.....	79
5.1	File>Export Data	79
5.2	File>Export Events - Creating *.txt File.....	79
5.3	Tools>Export/Delete	79
5.4	Tools>Export General Settings	79
5.5	Transferring a Study to Itamar Medical	79
6	TOOLS	84
6.1	Tools>Export/Delete	84
6.2	Tools>Import	87
6.3	Tools>Backup.....	89
6.4	Tools>Restore.....	89
6.5	Tools>Export General Settings	90
6.6	Tools>Import General Settings	91
6.7	Tools>User Administration.....	91
7	DATABASE WIZARD	92
7.1	Database Tools	93
7.2	User Administration	95
7.3	Configuration Tools.....	95
8	TROUBLESHOOTING	97
	APPENDIX A: LICENSE AGREEMENT	101
	APPENDIX B: TECHNICAL SUPPLEMENT	107

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APPENDIX C: KEYBOARD SHORTCUTS..... 111

APPENDIX D: MANUAL SLEEP DATA SIGNAL TRANSFER..... 112

APPENDIX E: INDEX..... 113

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List of Figures

Figure 1 - USB attachment to the PC.....	5
Figure 2 - zzzPAT installation dialog box	6
Figure 3 - zzzPAT License Agreement.....	6
Figure 4 - Customer Information dialog box.....	7
Figure 5 - Database Properties dialog box	7
Figure 6 - Database Destination dialog box	8
Figure 7 - Choose folder dialog box.....	9
Figure 8 - Application folder dialog box.....	9
Figure 9 - Ready to Install dialog box	10
Figure 10 - Database Properties with Advanced options dialog box	10
Figure 11 - Shared Database dialog box	11
Figure 12 - Database Properties Advanced (Client) dialog box	12
Figure 13 - Shared Database server dialog box.....	12
Figure 14 - Select Server dialog box	13
Figure 15 - Applications folder dialog box.....	13
Figure 16 - Installation completed dialog box.....	14
Figure 17 - Select USB Drive dialog box	16
Figure 18 - zzzPAT database Wizard dialog box.....	17
Figure 19 - User Administration dialog box	18
Figure 20 - User Details dialog box	19
Figure 21 - Select USB Drive dialog box	21
Figure 22 - Set Directories dialog box	21
Figure 23 - Save settings for current user question	22
Figure 24 - Setting Montage of zzzPAT display.....	23
Figure 25 - Setting colors of zzzPAT display	24
Figure 26 - Setting “Sleep Indices” report box.....	25
Figure 27 - General Settings Setting Dialog Box – Events Tab	26
Figure 28 - Save settings question.....	26
Figure 29 - General Settings Dialog Box – Medical History Tab.....	27
Figure 30 - General Settings Dialog Box – Medications Tab.....	29
Figure 31 - General Settings Dialog Box – Custom Fields Tab	30
Figure 32 - Define Values List Dialog box.....	31
Figure 33 - General Settings Dialog Box – General Options Tab	32
Figure 34 - Label example	33
Figure 35 - General Settings Dialog Box – Report Appearance Tab	34
Figure 36 - General Settings Dialog Box – Report Translation Tab.....	35
Figure 37 - Login Dialog Box.....	37
Figure 38 - New Study Dialog Box for WP100	39
Figure 39 - New Study Dialog Box for WP200	40
Figure 40 - Compact Flash Card/WP200 Not Loaded Dialog Box	41
Figure 41 - New Study Termination Question.....	42
Figure 42 - Demographic Details Dialog box.....	44
Figure 43 - Patient Clinical Data Dialog box.....	45
Figure 44 - More Study Details Dialog box	46
Figure 45 - Loading Study dialog box	48
Figure 46 - Select Patient Study dialog box	49

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Figure 47 - Select studies option	50
Figure 48 - zzzPAT display screen	51
Figure 49 - Selecting the All night Window	52
Figure 50 - All Night pop-up Menu	53
Figure 51 - Signal Properties – All Night window	53
Figure 52 - All Night pop-up menu	54
Figure 53 - Active channel pop-up menu	55
Figure 54 - zzzPAT screen Status Bar	55
Figure 55 - Set Channels View Dialog Box	56
Figure 56 - Set y-Scale dialog box.	57
Figure 57 - Set y-Scale – per channel dialog box	57
Figure 58: Add Event dialog box	61
Figure 59 - Event Type Search options	62
Figure 60 - Select Event dialog box	62
Figure 61 – Editing sleep stages	63
Figure 62 - Report Toolbar	63
Figure 63 - Clinical Diagnosis dialog box	64
Figure 64 - New Analysis Warning message	65
Figure 65 - Snoring and Body Position Statistics	66
Figure 66 - First page of Sleep Report	67
Figure 67 - Second page of Sleep Report	68
Figure 68 - Third page of Sleep Report (USA version)	69
Figure 69 - Third page of Sleep Report (non-USA version)	70
Figure 70 - Sleep Report for Selected Time Range Title	71
Figure 71 - Event Report	72
Figure 72 - Detailed Event Report	73
Figure 73 - Sleep Indices report	73
Figure 74 - Patient Follow Up Report (USA version)	75
Figure 75 - Letter to the Patient	77
Figure 76 - Print dialog box	78
Figure 77 - Launching Transfer Files	80
Figure 78 - Prepare and Send Study Dialog Box	80
Figure 79 - Saving Case Study	81
Figure 80 - Sending Study Confirmation	82
Figure 81 - Data Transfer Progress	82
Figure 82 - Data Transfer Successfully Completed	83
Figure 83 - Export Dialog box	84
Figure 84 - Delete studies options Dialog box	85
Figure 85 - Study Selection Dialog box	86
Figure 86 - Import Dialog Box	87
Figure 87 - Select Archive Dialog box	88
Figure 88 - Restore Dialog box	89
Figure 89 - Export General Settings Dialog Box	90
Figure 90 - Import General Settings Dialog Box	91
Figure 91 - Database Wizard Login	92
Figure 92 - Database Wizard	93
Figure 93 - Database Tools Wizard dialog box	94
Figure 94 - Configuration Tool Wizard	95

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List of Tables

Table 1 - User Permissions 19
Table 2 - Troubleshooting, Installation 97
Table 3 - Troubleshooting, zzzPAT 98
Table 4 - Troubleshooting, Shared Access Mode zzzPAT 99
Table 5 - Troubleshooting, Utilities 100

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1 Introduction to the zzzPAT

1.1 Intended Use of the Watch-PAT100 & Watch-PAT200

The Watch-PAT100 ("WP100") and Watch-PAT200 ("WP200") are non-invasive home care devices for use with patients suspected to have sleep related breathing disorders. The WP100 and WP200 devices are used as a diagnostic aid for the detection of sleep-related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep and Deep Sleep). The devices generate a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification ("PSTAGES"). The devices' "PSTAGES" provides supplemental information to its PRDI/PAHI. The devices' "PSTAGES" is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WP100 and WP200 are not indicated for children less than 17 years old.

1.2 The zzzPAT S/W – Definition

The zzzPAT is an analysis software package used with the WP100 or WP200 devices to aid in diagnosis of sleep related breathing disorders and detects REM, Light Sleep, Deep Sleep and Wake stages. The zzzPAT S/W displays the signals recorded by the WP100 or WP200 devices, automatically identifies breathing disordered events and REM, Light Sleep, Deep Sleep stages, and generates a comprehensive report for the physician.

1.3 Overview

Obstructive sleep apnea syndrome (OSAS) is considered a major public health problem. The prevalence of the syndrome is estimated at 2% to 5% in the adult population. It is characterized by recurrent events of complete or partial obstruction of the upper airways during sleep, often leading to hypoxemia, and/or arousals associated with sympathetic nervous system activation. The diagnosis and assessment of the sleep apnea patient is based on the Respiratory Disturbance Index (RDI), the number of Apneas, Hypopneas and Respiratory Effort Related Arousals (RERA) per hour of sleep and/or apnea-hypopnea index (AHI), along with sleep architecture. The common consequences of this sleep disruption are daytime sleepiness, poor daytime performance and increased vulnerability to accidents. Cardiovascular complications such as systemic/pulmonary hypertension, ischemic heart disease and arrhythmias are the major sequel of OSAS in the adult population.

The WP100 and WP200 are worn on the wrist and utilizes a plethysmographic based finger-mounted probe, to measure the PAT (Peripheral Arterial Tone) signal. The PAT

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signal is a measurement of the pulsatile volume changes in the fingertip arteries which reflects the relative state of the arterial vasomotor activity, and thus indirectly the level of sympathetic activation. Peripheral arterial vasoconstriction, which mirrors sympathetic activation, is shown as attenuation in the PAT signal amplitude. The PAT signal is recorded continuously and stored on a removable flash disk along with pulse rate (derived from the PAT signal), data from a built in pulse-oximeter (the sensor is mounted on an adjacent finger) and an actigraph (embedded in the device). Following the sleep study, in an offline procedure, the recordings are automatically downloaded and analyzed using the proprietary zzzPAT software.

The zzzPAT algorithms use the four WP100 or WP200 channels (PAT, Pulse Rate, Oxygen saturation and actigraphy) for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM), Light Sleep, Deep Sleep and Wake). The software issues comprehensive reports of the study, with statistics and graphic presentation of the results. The whole night data can be viewed and the automatically detected events can be revised manually.

This manual provides the information necessary for routine use of the zzzPAT software.

Restrictions

The tracings and calculations provided by the WP100 or WP200 systems are intended as an aid for Sleep Breathing Disorders diagnosis. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis.

- The zzzPAT software should be used only on compatible computers that meet the requirements specified in this document.
- Running other programs, commercial or customized, simultaneously with the zzzPAT may interfere with its proper function.
- zzzPAT may not function properly under Windows XP when multiple sessions are running (i.e. when more than one user is logged on to the same PC simultaneously, and each user is running zzzPAT).
- zzzPAT is not supported on Windows XP in remote mode.

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2 Installation

2.1 Overall Description of zzzPAT Software

zzzPAT is a proprietary PC software developed specifically for managing and analyzing data recorded by the WP100 and WP200 devices. The software displays and stores the recorded signals, and provides a set of analytical functions for interpretation purposes.


A Compact Flash reader (drive) is used to read the data recorded by the WP100 on a Compact Flash card. Please refer to Section 2.2 for required PC configuration.

A USB cable is used to read the data recorded by the WP200 on the internal SD card. The zzzPAT S/W automatically detects the data on the internal SD card once the WP200 is connected to the PC via the USB communication cable.

zzzPAT can operate in two modes:

Standalone - for use on a single PC with a local database.

Shared Access - for use in a networked environment where multiple zzzPAT stations access a single, shared database.

	<p style="text-align: center;">Note</p> <p>It is strongly advised to coordinate the setting of shared access zzzPAT operation mode with an Itamar Medical representative. Extra training is crucial for proper operation.</p>
--	---

The zzzPAT mode of operation is determined during installation as further described in the Installation section of this operation manual.

A Compact Flash reader (drive) is used to read the data recorded by the WP100 on a Compact Flash card. Please refer to Section 2.2 for required PC configuration.

2.2 Hardware Requirements

2.2.1 Hardware configuration

Computer Pentium 3 450MHz minimum / Pentium 4 1GHz or higher recommended

CD-ROM drive

1 available USB port / Additional serial port is recommended

XGA screen resolution (minimum 1024 x 768 pixels)

Colors set to 16 bits or higher


RAM 256MB minimum

Free disk space: 10GB minimum / 60GB recommended disk on database drive and at least 1.2GB on boot drive


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2.2.2 Operating System

Windows XP with Service Pack 2 and above
Windows Vista Home Premium
Windows Vista Enterprise
Windows Server 2003

	<p style="text-align: center;">Note</p> <p>Software components needed for the proper installation of zzzPAT should be installed prior to zzzPAT installation (OS service packs or latest OS updates).</p>
---	--

2.3 Installation of the Compact Flash drive

	<p style="text-align: center;">Note</p> <p>Refer to the installation instructions provided with the Compact Flash drive.</p>
--	---

- **WP100 device only:** The provided Compact Flash drive may require the installation of a driver depending on the Windows operating system version and the type of Compact Flash drive. Please refer to the instructions provided with the Compact Flash drive for installation instructions.

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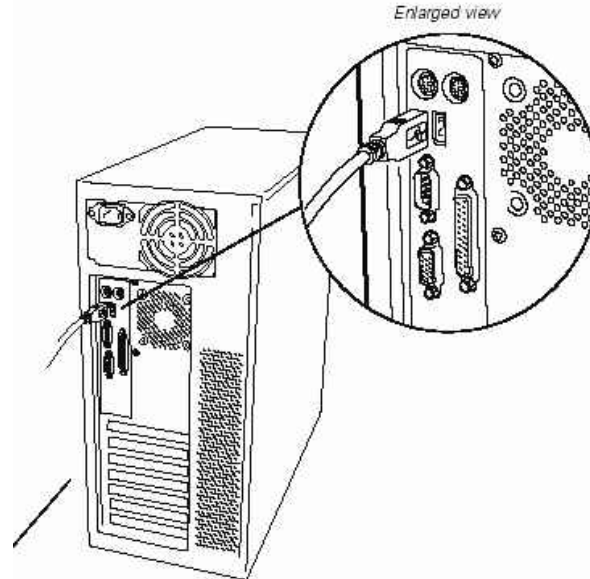



Figure 1 - USB attachment to the PC

2.4 Installing zzzPAT software

This process will install a single icon  on the desktop, which opens the zzzPAT analysis and reporting software. To open the New Study and Database Wizard applications, use the Start>Programs>zzzPAT command.

Quick start instructions:

- **WP100 device only:** Verify that the Compact Flash drive is installed and plugged to the PC.
- Insert the zzzPAT CD into the computer's CD-ROM drive.
- If the CD-ROM drive is set to run automatically, the installation will begin automatically. If installation does not begin, refer to the section below.
- Follow the instructions on the screen.

If the installation does not start automatically

- Double-click the My Computer icon on your desktop.
- Double-click the CD-ROM icon labeled zzzPAT.
- Double-click 'Setup.exe'.
- Follow the instructions on the screen.

You are now ready to run the zzzPAT software. See section 2.9 for instructions "Before using zzzPAT Software for the first time".

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2.5 Step by step installation instructions

Prior to installation, verify that you are in full system administrator mode with full privileges.

1. Insert the zzzPAT installation CD into the CD drive. The installation program is activated, and the following dialog box appears. If the installation does not start automatically refer to section 2.4.

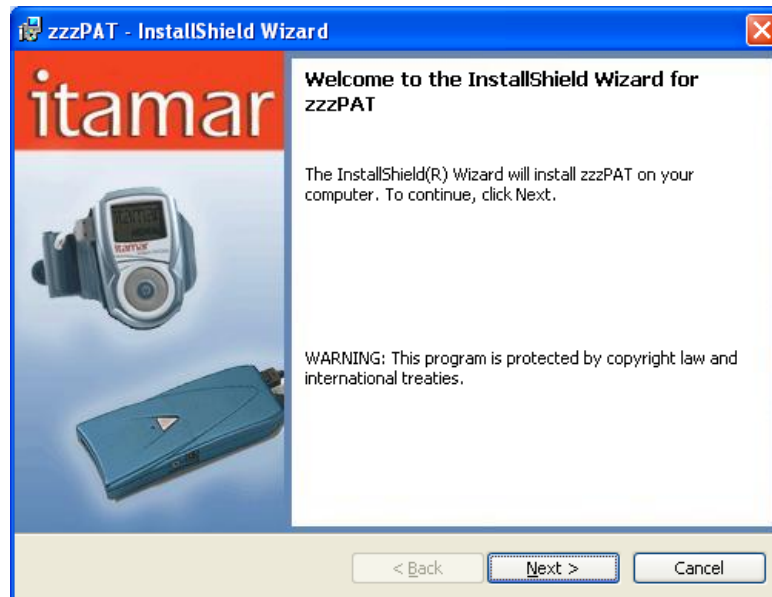


Figure 2 - zzzPAT installation dialog box

2. Click **Next**. The License Agreement appears.

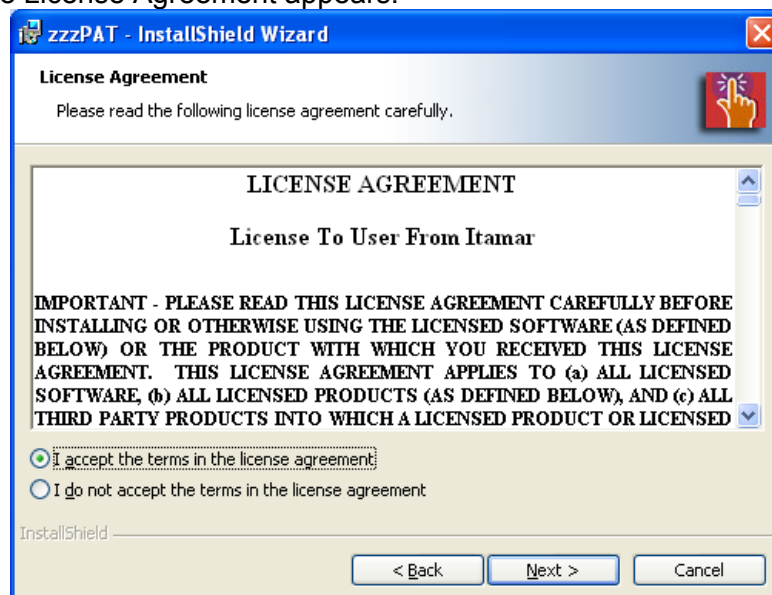


Figure 3 - zzzPAT License Agreement

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3. After reading the agreement, select **I accept the terms in the license agreement** and click **Next >** to continue.
The 'Customer Information' dialog box appears.

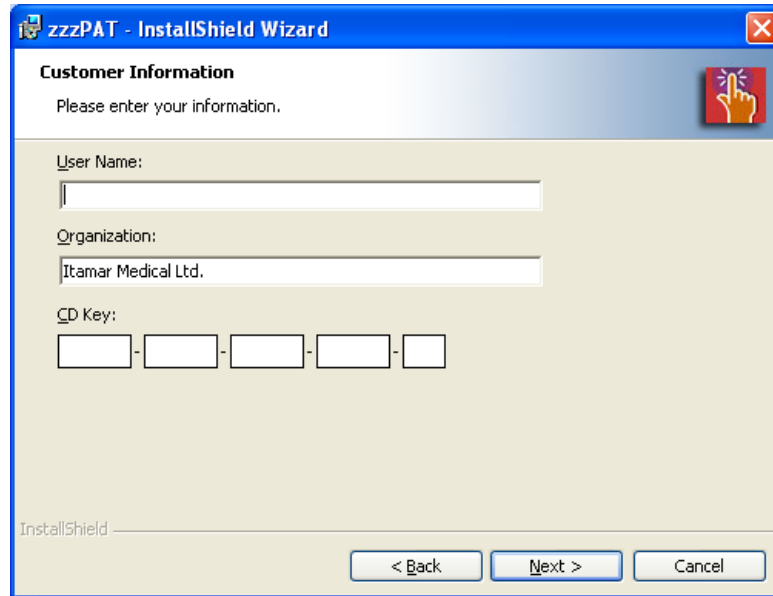


Figure 4 - Customer Information dialog box

4. Enter user name, company name and the serial number exactly as it appears on the cover of the zzzPAT installation disk.
5. Click **Next>** to continue.
The 'Database Properties' dialog box appears.

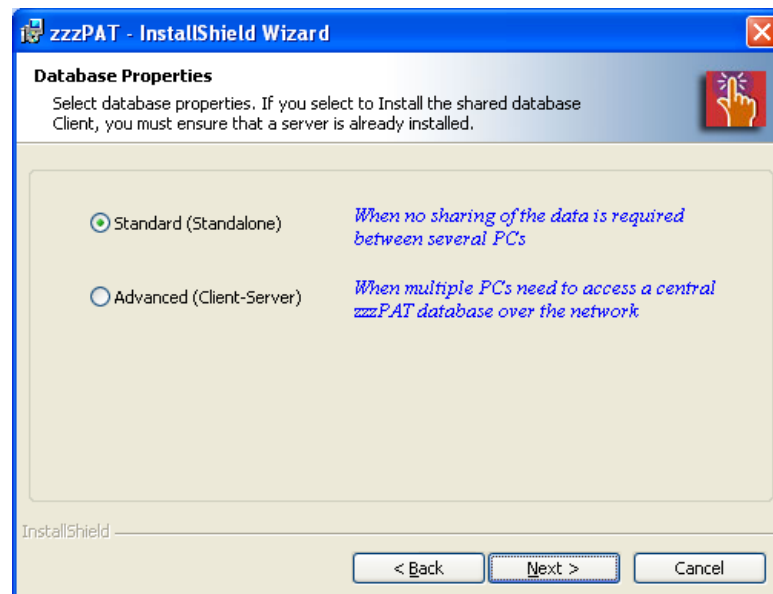


Figure 5 - Database Properties dialog box

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2.5.1 Installations types

The zzzPAT software can be installed as a standalone or as a client/server configuration.

- "Standalone" - intended for users that do not require sharing that database with other zzzPAT stations.
- "Client/Server" intended for network installations with multiple zzzPAT stations accessing a central zzzPAT database over the network. If you wish to install this mode it is strongly advised to coordinate the installation with an Itamar Medical representative. Extra training is crucial for proper operation.
 - The "Server" mode is selected **only once prior** to installing the "Clients". This installation should be done on the dedicated computer which will serve as the server for the zzzPAT clients.
 - The "Client" mode is selected **only after** installing the "Server" and is **repeated for all clients**.

2.5.1.1 Standard - Standalone installation only

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT database. If the necessary folder does not exist, zzzPAT Installer will create the folder.

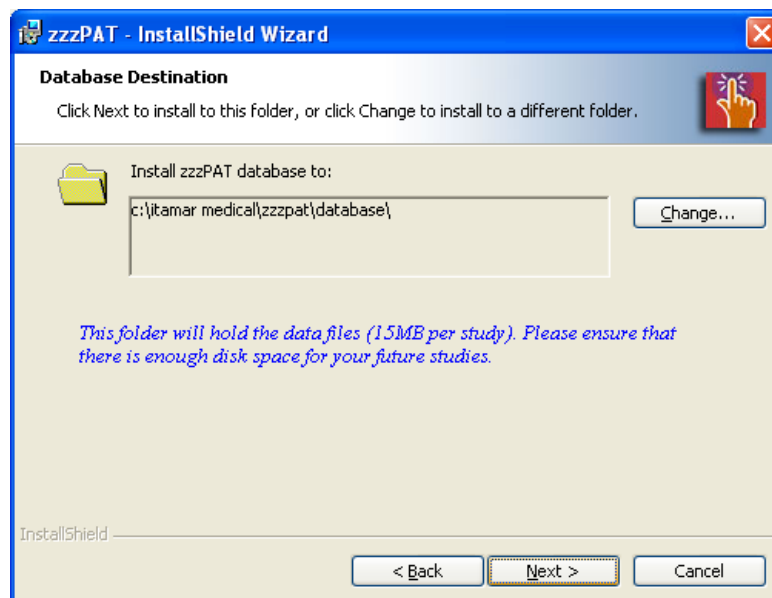


Figure 6 – Database Destination dialog box

If you wish to change the default folder, select the Change button. The 'Choose Folder' dialog appears.

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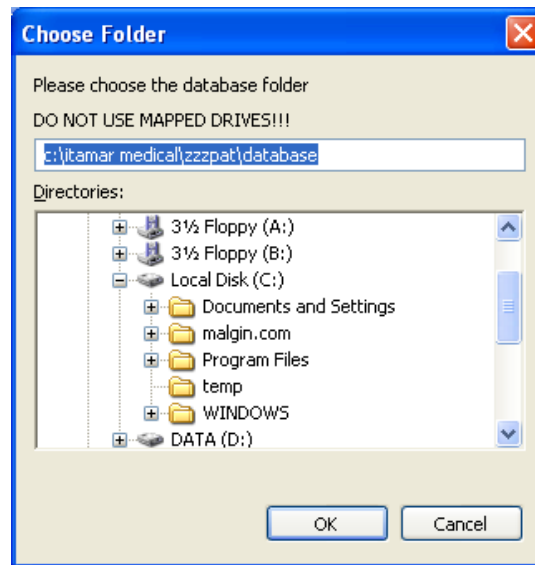


Figure 7 – Choose folder dialog box

Make sure you are not selecting a mapped drive. Select **OK** to Proceed.
The zzzPAT Installer will assist in selecting a destination location for the zzzPAT application files. If you wish to change the default folder, select the Change button.



Figure 8 – Application folder dialog box

The last dialog before standalone installations summarizes your selections.
After reading this summary, press **Install** to begin the installation.

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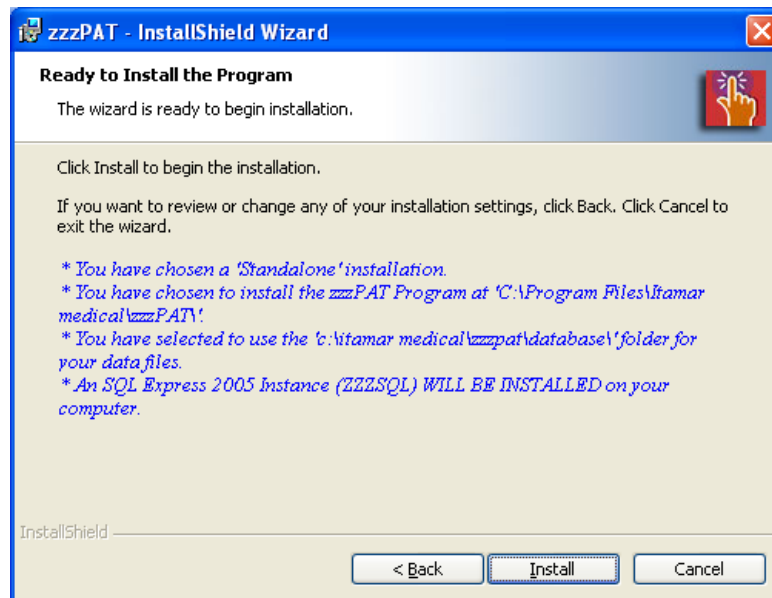


Figure 9 – Ready to Install dialog box

2.5.1.2 Advanced - Server installation only

The following selection will result in Server installation

The Server side installation creates a shared MS-SQL database that is used by multiple zzzPAT stations. Accordingly, the shared database needs to be created **only once per site installation**.

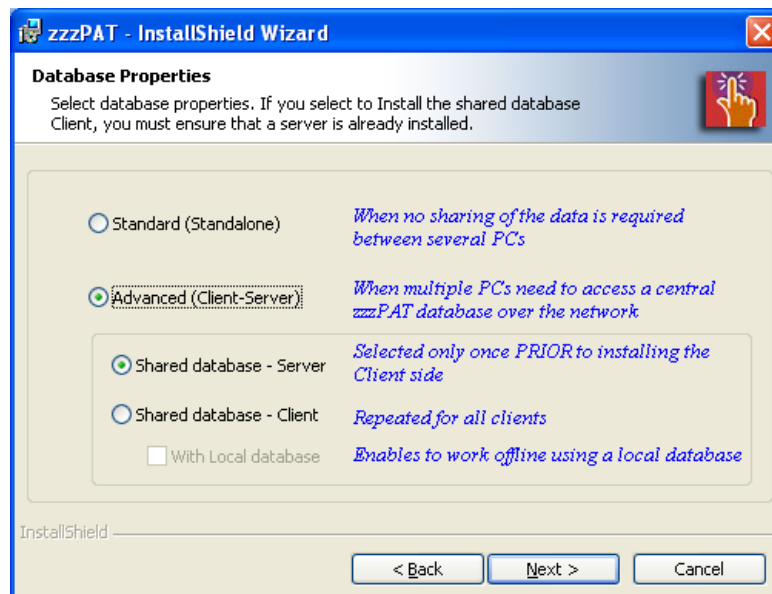


Figure 10 – Database Properties with Advanced options dialog box

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT database.

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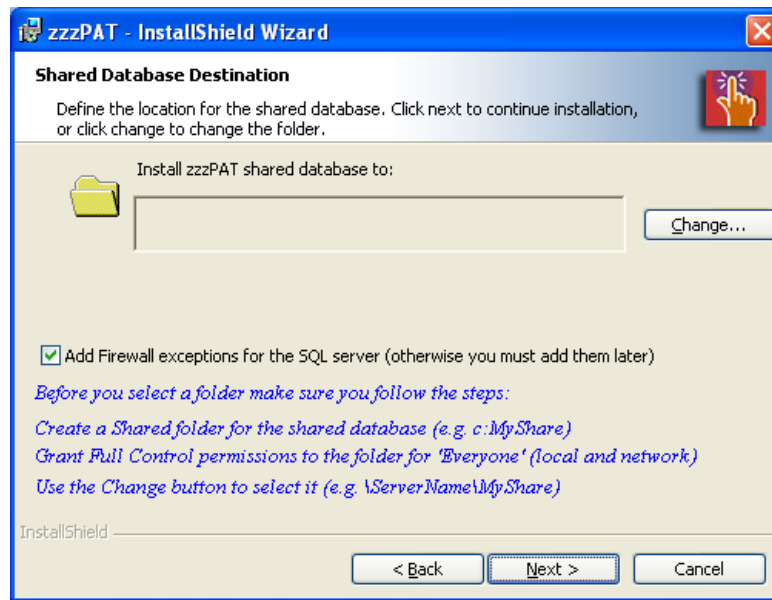



Figure 11 – Shared Database dialog box

Press the Change button to enter a UNC path for the database files folder. This folder will be accessed by all zzzPAT users so it needs to be shared in the network with full control permissions for the "Everyone" group.

	<p style="text-align: center;">Note</p> <p>If you do not want to use the "Everyone" group, please define a group of "zzzPAT" users and grant this group Full Access to this shared folder. In that case you will have to grant the same permissions to the following services:</p> <ul style="list-style-type: none">SQL Server (ZZZSQL)SQL Server VSS WRITER
---	---

The last dialog prior to beginning server installation summarizes your selections. After reading this summary, press **Install** to begin the installation.

2.5.1.3 Advanced - Client installation only

The following selection will result in Client installation

Prior to performing a Client side installation a Shared Database installation must be previously performed on a given PC.

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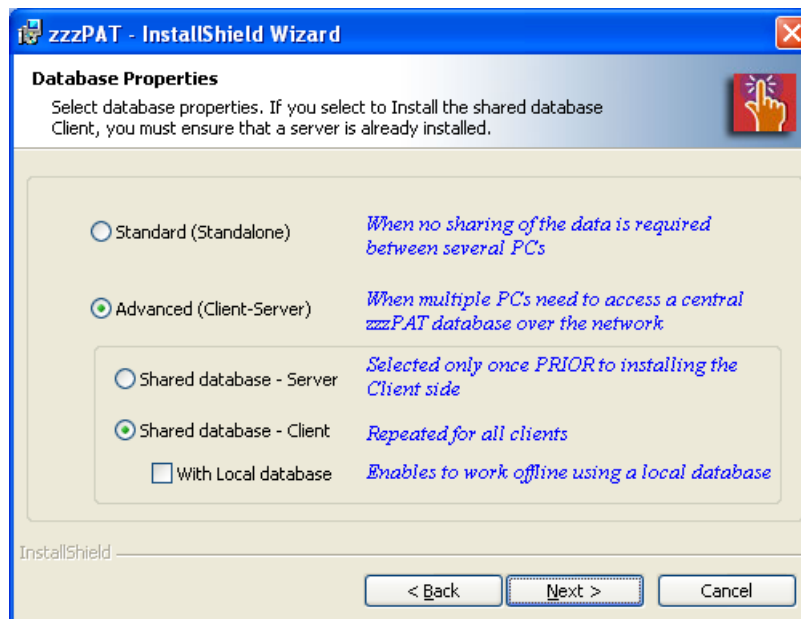


Figure 12 – Database Properties Advanced (Client) dialog box

The Client installation may also have a local database and during zzzPAT login the user can select to connect to the Shared or Local database. For this option you should check the “With Local database” check box.

It is not recommended to install the local database option unless offline work is anticipated with the particular computer.

Press **Next** to define the Shared Database.

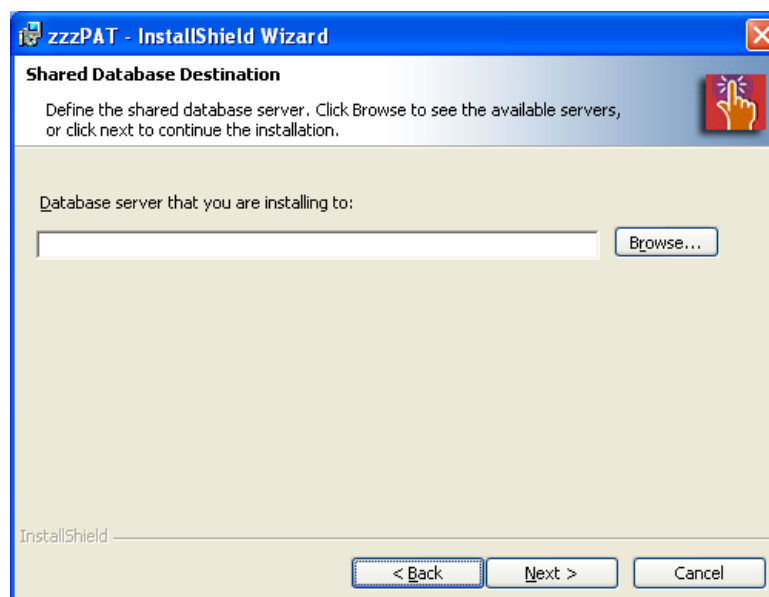


Figure 13 – Shared Database server dialog box

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You can also enter the <name of the computer with the SQL server>\ZZZSQL , i.e. SQL_PC\ZZZSQL

The zzzPAT installer will identify and display the currently defined database servers. Click Browse to see the ZZZSQL servers. The shared MS-SQL database can be selected from the list.

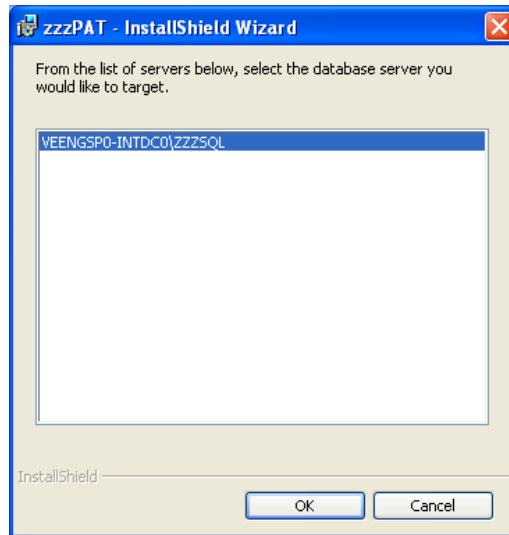


Figure 14 – Select Server dialog box

The zzzPAT Installer will assist in selecting a destination location for the zzzPAT application files. If you wish to change the default folder, select the Change button.



Figure 15 – Applications folder dialog box

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Press **Next** to proceed.

The last dialog before client installation summarizes your selections.
After reading this summary, press **Install** to begin the installation.

At the end of the installation the final dialog is displayed.

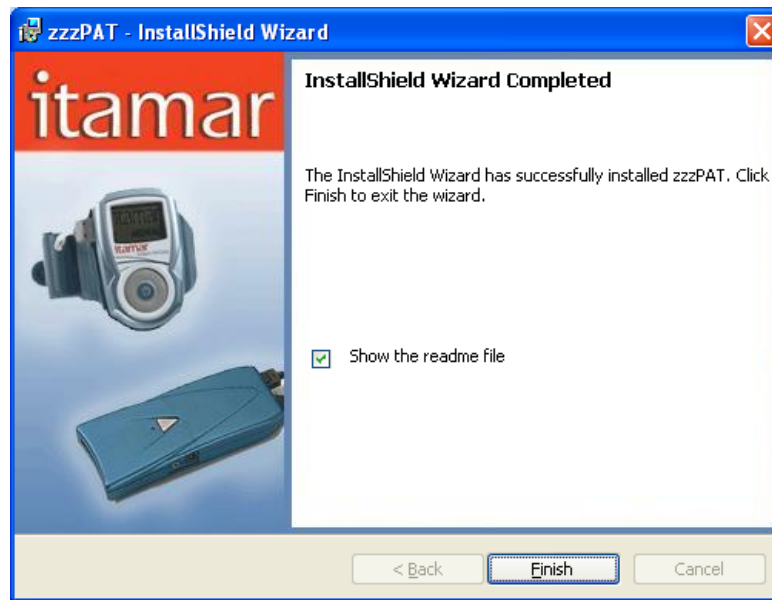


Figure 16 – Installation completed dialog box

At the end of the installation you should restart your computer


	<p style="text-align: center;">Note</p> <p>A login name and password are needed to operate this software. The default administrator login information is: Login name: 111 Login password: 111 To modify the administrator login name and password, and to add/modify additional users, refer to section 2.9.</p>
	<p style="text-align: center;">Warning</p> <ul style="list-style-type: none">• Do not attempt to modify the zzzPAT software.• It is recommended to close other programs when using zzzPAT to prevent possible conflicts.

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2.6 Upgrading from previous versions

2.6.1 Upgrading a Standalone Installation


Before upgrading from a previous zzzPAT version, the older version must be uninstalled. The zzzPAT installer will identify if the older version has not been removed and will prompt you to uninstall it.

	<p style="text-align: center;">Note</p> <p>Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT</p>
---	---


- Backup the entire database of the existing zzzPAT installation (see Database Wizard, Backup section 7.1.3).
- Uninstall the previous version using 'Add/Remove Programs' applet from the control panel.
- Select 'Setup.exe' from the zzzPAT installation CD-ROM to start the zzzPAT installation program.
- Follow stages 1-6 in section 2.5.

2.6.2 Upgrading a Shared Database Installation

Activating the Shared Database installation on an older version zzzPAT station will update the zzzPAT software only – the database will not be updated through the installer and will require a separate upgrade process described later in this section.

	<p style="text-align: center;">Warning</p> <p>An upgraded zzzPAT will not always work with older versions of the database. Once an upgrade to a Shared Access installation zzzPAT station is made, both the local and shared access databases must be updated to the correct version before the zzzPAT can be put to use again.</p>
---	--

Before upgrading from a previous version of the zzzPAT, the older version must be uninstalled. The zzzPAT installer will identify if the older version has not been removed, and will prompt you to uninstall.

	<p style="text-align: center;">Note</p> <p>Uninstalling zzzPAT does not remove the zzzPAT database, however, it is strongly recommended to backup the database before upgrading zzzPAT.</p>
---	--

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- Backup the entire database of the existing zzzPAT installation (see Database Wizard, Backup section 7.1.3).
- Select 'Setup.exe' from the zzzPAT installation CD-ROM to start the zzzPAT installation program.
- Uninstall the previous zzzPAT version using 'Add/Remove Programs' applet from the control panel.
- Follow stages 1-5 in section 2.5.

2.6.2.1 Upgrading Databases

The upgrade will be performed automatically the first time zzzPAT is launched following an upgrade of zzzPAT, only if the database folder remained the same as the previous installation.

2.7 Defining the USB drive

To prepare a new study (**File>New Study Details** from zzzPAT), you must first define the USB drive.

WP100 device only: Place the Compact Flash card supplied with the WP100 in the USB drive that is connected to the PC with the zzzPAT software.

WP200 device only: Connect the device to the PC's USB drive using the supplied USB cable.

- Click **File>New Study Details** in zzzPAT. A dialog box will open (see Figure 38).
- Click **Select USB Drive** in the 'New Study' dialog box. The following window will appear:

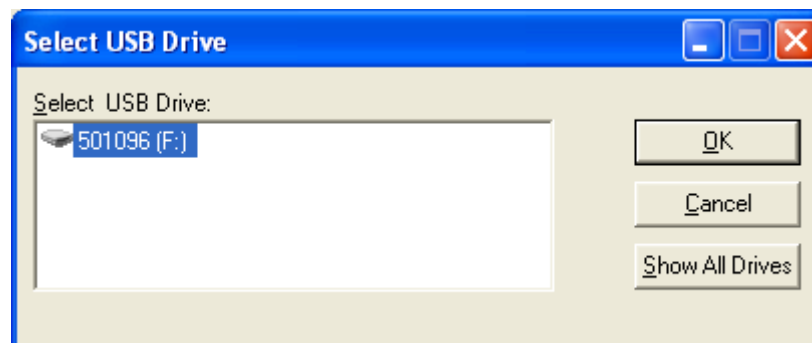


Figure 17 - Select USB Drive dialog box

- The USB drive with the Compact Flash card/WP200 device is identified by the zzzPAT, and is listed in this window. Click **OK** to confirm the drive selection.

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2.8 Opening an ftp reception account with Itamar Support.

Opening an ftp signal reception account at Itamar Support after installing zzzPAT, will allow fast and efficient support if needed later. To do so:

- Open a sample study.
- Follow the steps in section 5.5.

2.9 Before using zzzPAT Software for the first time

In order to maintain the security of the information stored by the zzzPAT, it is recommended that you set new administration Login and Password, replacing the default setting.


2.9.1 Setting new login and Password for the zzzPAT Administrator


- Select **Tools>User Administration** from zzzPAT or navigate through: **Start>Programs>zzzPAT>Database Wizard** (see 2.6.2).
- Log in using the system default settings (in Shared Access mode this process needs to be repeated twice – once for the shared access database and once for the local database):
- Login: 111
- Password: 111
- A dialog box will open – Figure 18 for **Start>Programs>zzzPAT>Database Wizard** or Figure 19 for **Tools>User Administration**.



Figure 18 - zzzPAT database Wizard dialog box


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- Click 'User Administration' icon . The 'User Administration' dialog box will open.
- Select 'Super User'.
- Click Edit User.
- Change the default Login from 111 to the new login.
- Change the default Password from 111 to a new password.
- Update the personal information.
- Click Save User.

	<p style="text-align: center;">Note</p> <p>In Shared Access mode changing the administrator login for the shared access database needs to be performed only once. Changes to the local database administrator login needs to be changed in each of the zzzPAT stations.</p>
---	--

2.9.2 Setting a New user

Setting new user Login and Password and defining the permissions allowed for each user operating the zzzPAT.

- Launch the 'Database Wizard' and Click 'User Administration' icon  (see Section 2.9.1) or select **Tools>User Administration** from zzzPAT.
- The following dialog box will open:

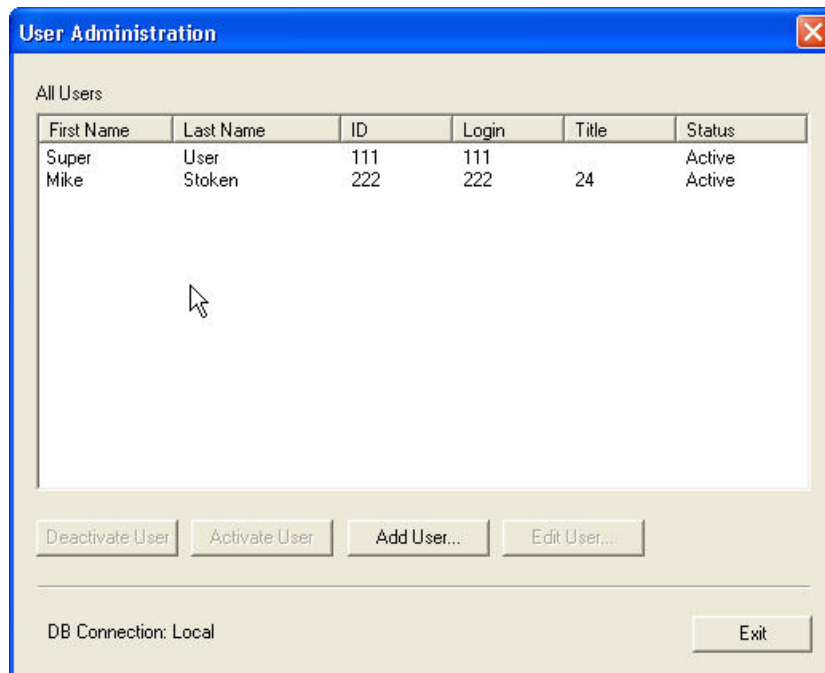


Figure 19 - User Administration dialog box

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- Click **Add User**. The following dialog box will open:

Figure 20 - User Details dialog box

- User Details:** Fill all user details fields. **Demographics** information is optional.
- Extended Permissions:** This section defines the functions each user is allowed to perform with the zzzPAT (see Table 1).


Extended Permissions	Allowed activities
No extended permissions selected	Basic User: <ul style="list-style-type: none"> Prepare a Compact Flash card for a new study Load study into zzzPAT Issue reports
Patient ID Modification	Basic User plus: <ul style="list-style-type: none"> Modify a patient's ID
Finalizing report	Basic User plus: <ul style="list-style-type: none"> Finalizing the report. This action locks the current analysis, so that no further changes can be made to the analysis and report.
Database Maintenance	Basic User plus: <ul style="list-style-type: none"> Database export, import, delete, backup, restore and upgrade functions. (See section 5)
System Administrator	Basic User plus: <ul style="list-style-type: none"> Adding users to zzzPAT and defining their permissions Customizing capabilities for the General Settings


Table 1 - User Permissions

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To deactivate a user:

- Click on the User's name in the 'User Administration' dialog box.
- Click Deactivate User.

	<p style="text-align: center;">Note</p> <p>Permanently removing a user from the system is not possible. User's information is part of the study records, and cannot be deleted.</p>
---	--

	<p style="text-align: center;">Note</p> <p>The original user (originally named "Super User") cannot be deactivated. It can only be modified with a new name and password to ensure continued access with System Administrator's privileges.</p>
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3 Setting Up zzzPAT Configuration

3.1 Setup>Set USB Drive

Sets the path to the Compact Flash drive (for WP100) or WP200 device.

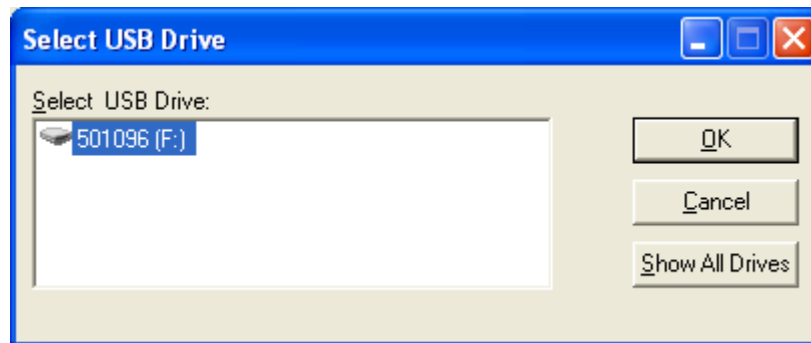


Figure 21 - Select USB Drive dialog box

3.2 Setup>Directories

Displays the zzzPAT working directory, the name of the currently connected database, the files directory (signal files data) and the USB drive.

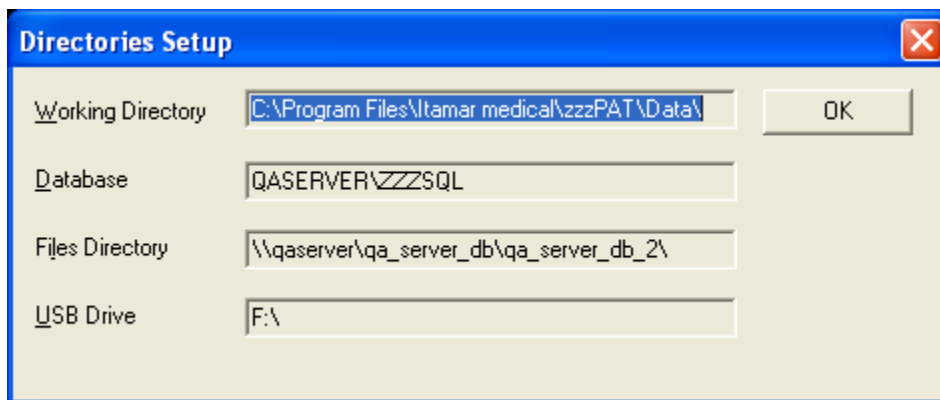



Figure 22 - Set Directories dialog box

3.3 Setup>User Settings

The user can change the following Setup parameters by opening the 'User Settings' dialog box from **Setup>User Settings**. 'User Settings' setup parameters are stored in the zzzPAT database for each user (either the local database in a standalone installation or the shared access database in a Shared Access installation).

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	<p style="text-align: center;">Note</p> <p>In a Shared Access mode, when a user logs in from several zzzPAT stations simultaneously, changes to some of the user configurable settings of zzzPAT may not be saved after the zzzPAT session ends</p>
---	--

When all settings changes are completed, click **OK** to close the Settings dialog box. The following dialog box will open:

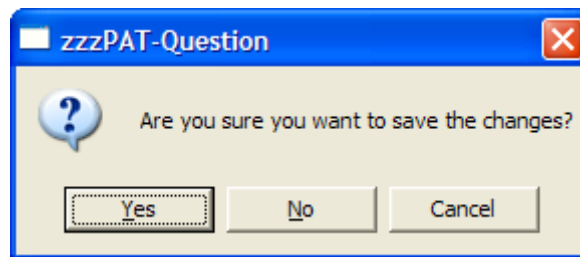


Figure 23 - Save settings for current user question

Clicking **Yes** will save the changes.

Clicking **No** will exit 'User Settings' Dialog Box.

Clicking **Cancel** will return the last displayed dialog box.

3.3.1 Setup>User Settings>Montage

Defines which channels will be presented on the zzzPAT screen, and in what order. This setting is saved in the 'User Profile' file.

The Montage page consists of a list of all signal channels available for viewing:

- PAT- PAT signal.
- Heart Rate - Derived from the PAT signal.
- PAT Amplitude - PAT signal envelope.
- SaO₂ - Arterial blood Oxygen saturation level.
- Actigraph - Actigraphy signal.
- WP100 or WP200 Stages – REM, Light Sleep, Deep Sleep and Wake stages.
- Body position
- Snore

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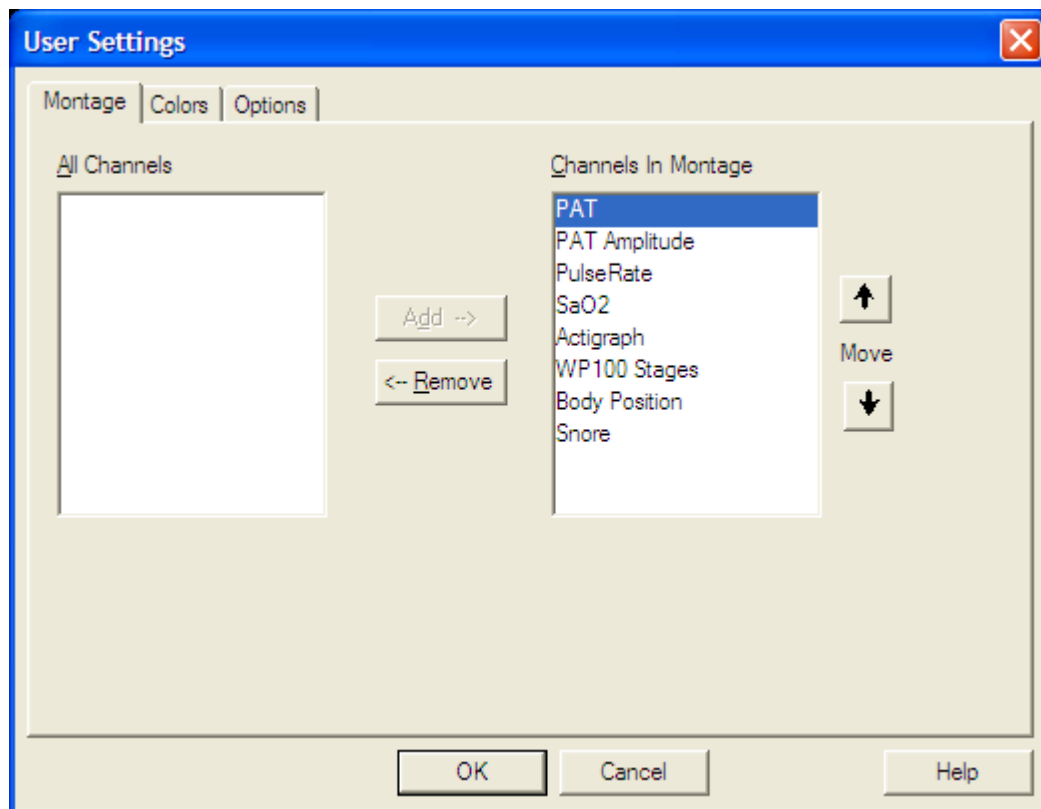


Figure 24 - Setting Montage of zzzPAT display

To add a channel:

- Select the channel in the 'All Channels' window and click **Add**.

To remove a channel:

- Select the channel in the 'Channels In Montage' window and click **Remove**.

To change the order of appearance of the channels:

- Select a channel and then click **↑** or **↓** until you reach the desired order.

3.3.2 Setup>User Settings>Colors

Colors Setup page (Figure 25) consists of a list of all the display elements that can be colored, allowing the user to personalize the screens. The example area provides a preview of the selected color scheme. This setting is saved in the 'User Profile' file.

To change a color:

- Select a display element from the list.
- Click the **Change Color** button to select a new color. The preview is displayed in the 'Example' area.

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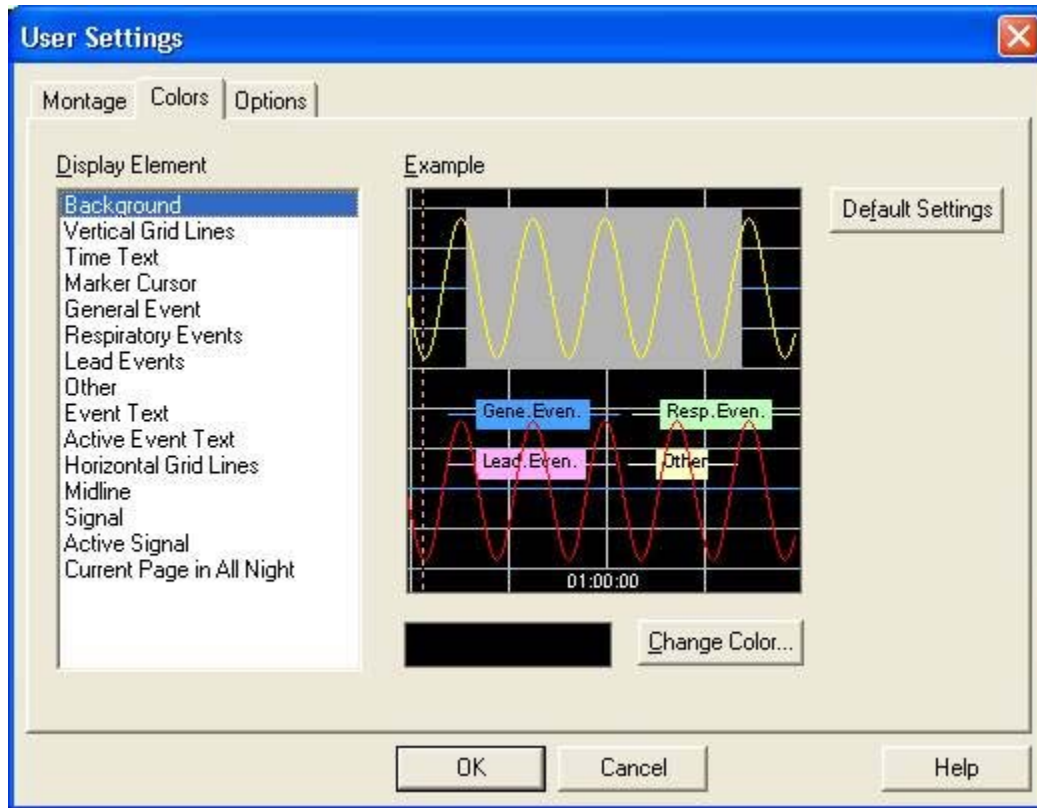



Figure 25 - Setting colors of zzzPAT display

	<p style="text-align: center;">Note</p> <p>Be careful not to choose a color that blends into one of the background elements</p>
---	--

3.3.3 Setup>User Settings>Options

Defines if and when the 'Sleep Report' or 'Sleep Indices' report is displayed automatically.

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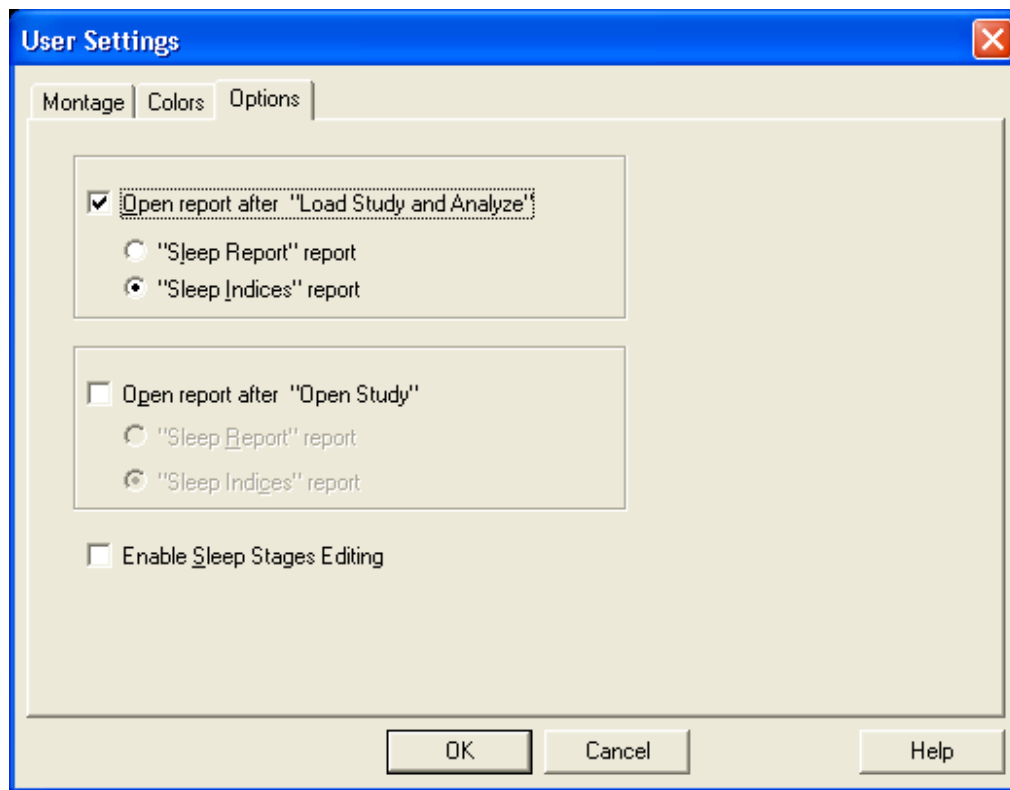


Figure 26 - Setting "Sleep Indices" report box

You can select to open a report either after "Load Study and Analyze" by selecting 'Open report after "Load Study and Analyze"' or/and for existing study by selecting 'Open report after "Open Study"'. Both options contain radio-buttons that enable you to select between Sleep Report and Sleep Indices report.

- When selecting "Sleep Report" report, the sleep report opens automatically.
- When selecting "Sleep Indices" report, the sleep indices report appears automatically on display, and the sleep report opens upon command.

You can select "Enable Sleep Stages Editing" if you want to be able to edit manually the Sleep stages (see Editing Sleep Stages).

3.4 Setup>General Settings

Only a user, with 'User Administration' permission, can change the following Setup parameters by opening the 'General Settings' dialog box from **Setup>General Settings**. 'General Settings' are stored in the zzzPAT database (either the local database in a standalone installation or the shared access database in a Shared Access installation).

These settings are global. Modified settings become available to all users.

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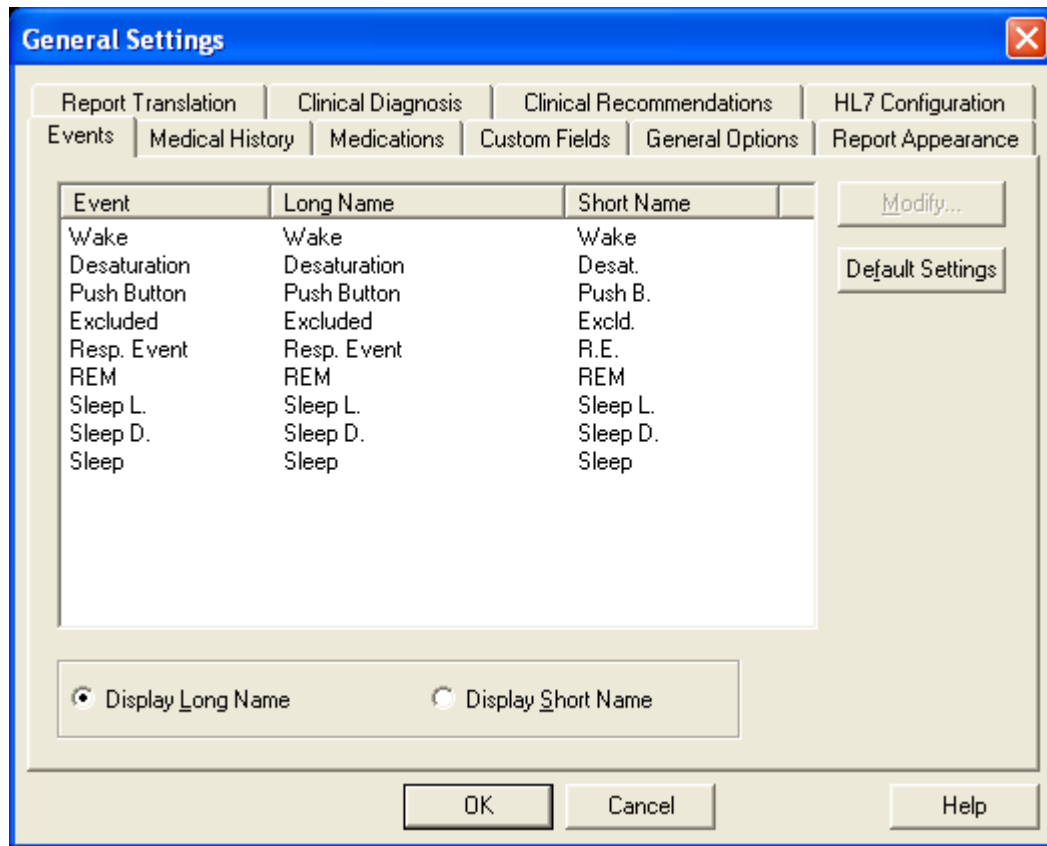


Figure 27 - General Settings Setting Dialog Box – Events Tab

When all settings changes are completed, click **OK** to close the General Settings dialog box. The following dialog box will open:

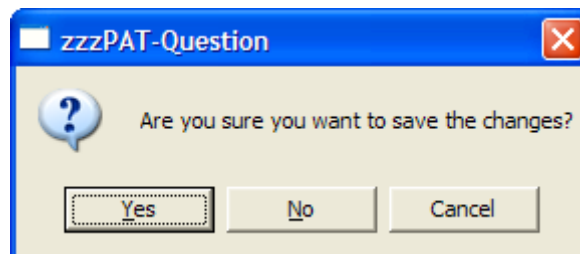


Figure 28 - Save settings question

Clicking **Yes** will save the changes.
 Clicking **No** will exit 'General Settings' dialog box.
 Clicking **Cancel** will return the last displayed dialog box.

3.4.1 Setup>General Settings>Events


A list of Event types is listed in the events tab (Figure 27). The list includes event type, long name, short name and category for each event.

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To Modify an Event in the Settings list:

- Click on the Event in the list box. The **Modify** and **Default Setting** buttons become enabled.
- Click the **Modify** button. 'Modify Event Definition' dialog opens.
- Enter the required names in the fields.
- Click 'OK' to confirm and exit.

Default Settings reverts to the default event list.

	<p style="text-align: center;">Note</p> <p>Clicking the Default Settings will revert to default settings losing all user-defined settings.</p>
---	--

3.4.2 Setup>General Settings>Medical History

A preliminary list of medical condition descriptions is listed in the Medical History Tab (Figure 29).

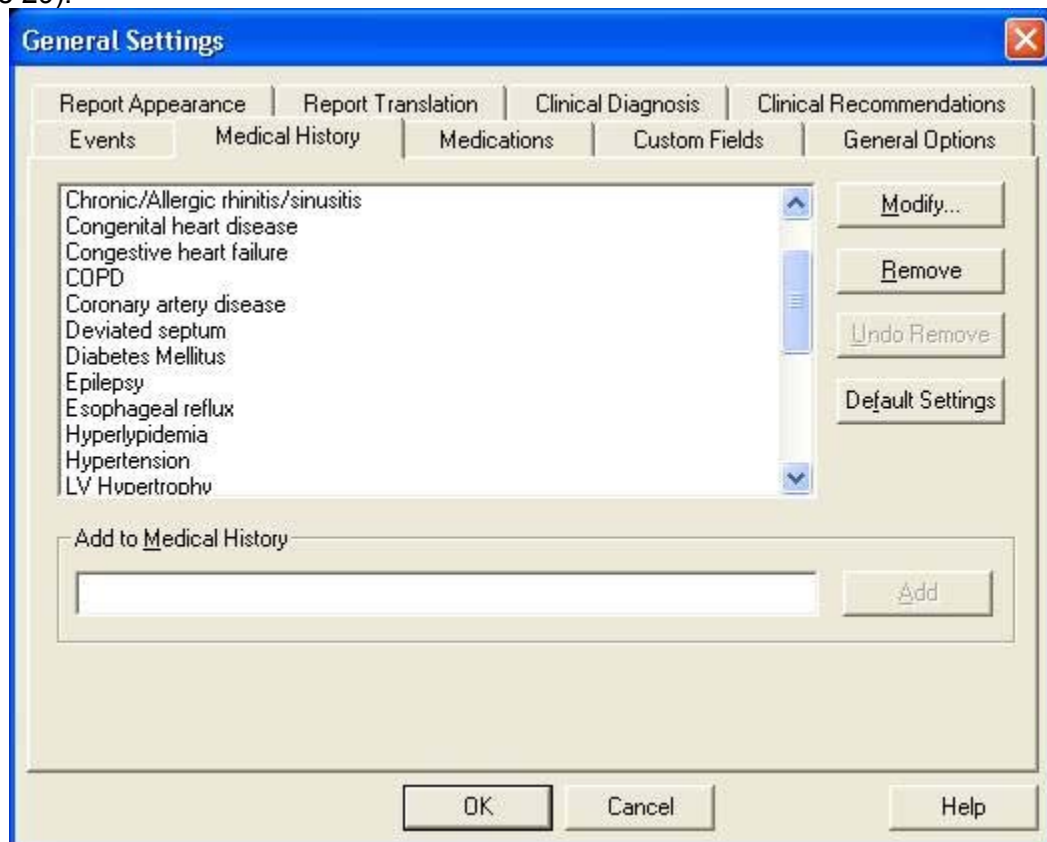


Figure 29 - General Settings Dialog Box – Medical History Tab

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To add a condition to the list:

- Type the condition in the 'Add to Medical History' box. The **Add** button becomes enabled.
- Click **Add**.

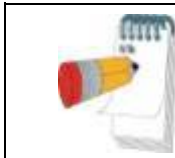
To modify a condition:

- Click on the condition.
- Click **Modify**. The 'Modify' dialog box opens with the selected condition name.
- Type in the desired changes.

To remove a condition from the list:

- Click on the condition.
- Click **Remove**.
- Click **OK** or **Apply**.

Default Settings reverts to the default list.



Note

Clicking the **Default Settings** will revert to default settings losing all user defined setting.

3.4.3 Setup>General Settings>Medications

A default list of Medications is listed in the medication tab.

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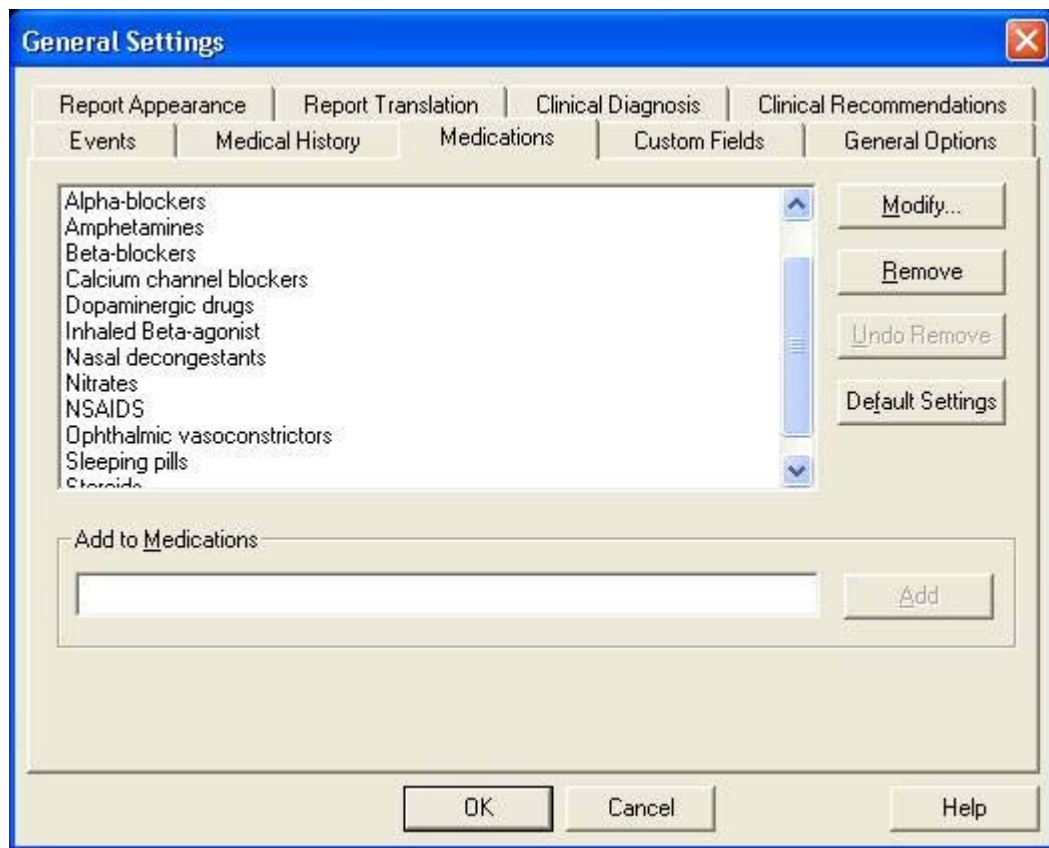


Figure 30 - General Settings Dialog Box – Medications Tab

To add a Medication to the list:

- Insert Medication name in the 'Add to Medication' text box. The **Add** button becomes enabled.
- Click **Add**.


To modify a Medication:

- Click on the listed Medication.
- Click **Modify**. The Modify dialog box opens with the selected Medication name.
- Type in the change requested.

To remove a Medication from the list:

- Click on the listed Medication.
- Click **Remove**.

Default Settings reverts to the default list.

	<p style="text-align: center;">Note</p> <p>Clicking the Default Settings will revert to default settings losing all user defined setting.</p>
---	---

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3.4.4 Setup>General Settings>Custom Fields

Up to three 'Custom Fields' can be defined and named by the user. These 'Custom Fields' can be used to organize your studies in the 'Select Patient Study' dialog box (Figure 46) and during the Export/Import process. These custom fields are available to all users.

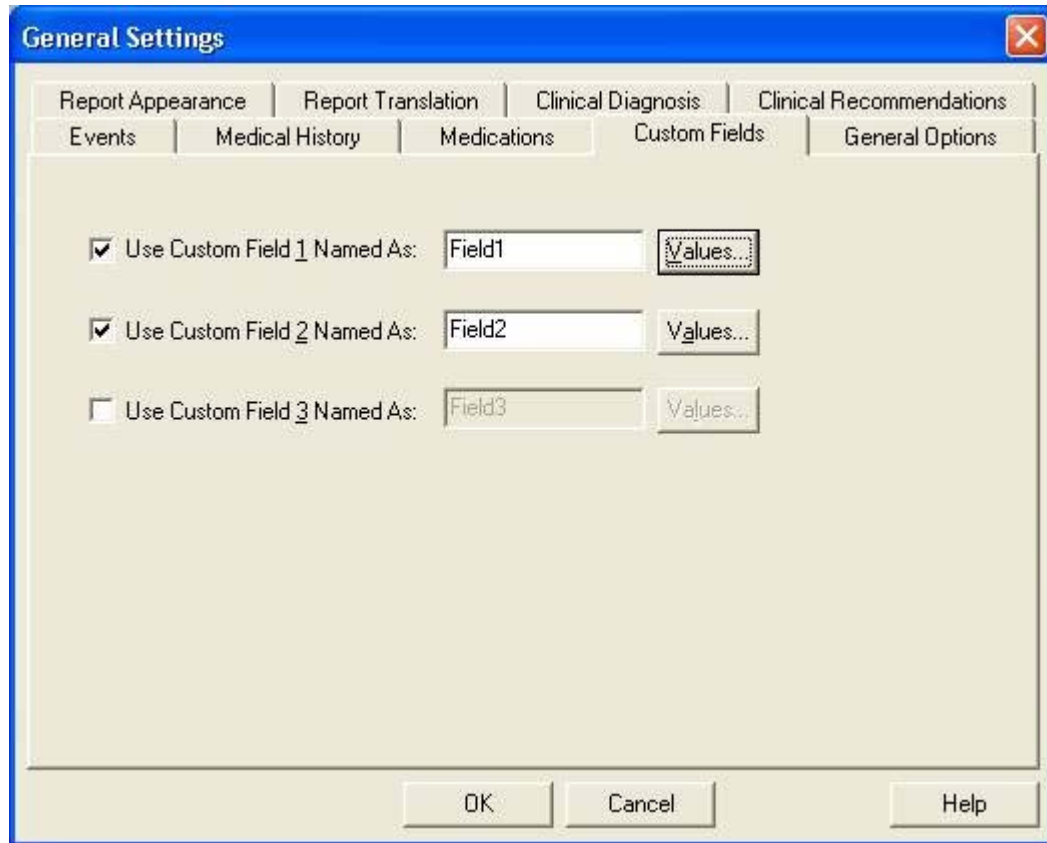


Figure 31 - General Settings Dialog Box – Custom Fields Tab

To enable a custom field:

- Check the box to the left of the custom field. The **Values** button becomes enabled.
- Write the title of your choice for this field in the text box (for example CHF).
- Click the **Values** button, the following dialog box will open:

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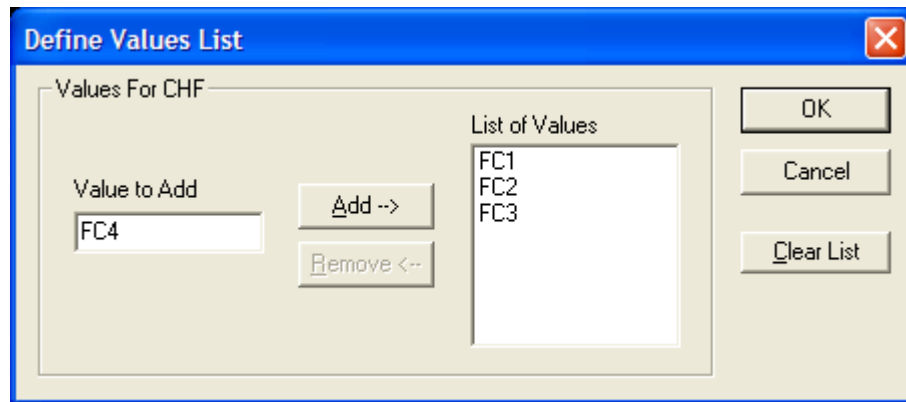


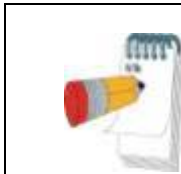
Figure 32 - Define Values List Dialog box

To insert a value into the 'List of Values' field:

- Write a value you wish to insert into the 'Value to add' text box, the **Add** and **Remove** buttons will become enabled.
- Click **Add**.

To delete a value from the list of values you created:

- Click on the value and click **Remove**.
- Click **OK** to save settings.



Note

Defining values can assist you when entering the information into these fields while preparing a 'New Study', but you can also type free text values into these fields.

3.4.5 Setup>General Settings>General Options

Used to set up reminders to backup the database, alerts when available disk space is below 1GB and in order to enable features that not enabled by default (import packed studies, multi-night studies and tamper-proof testing).

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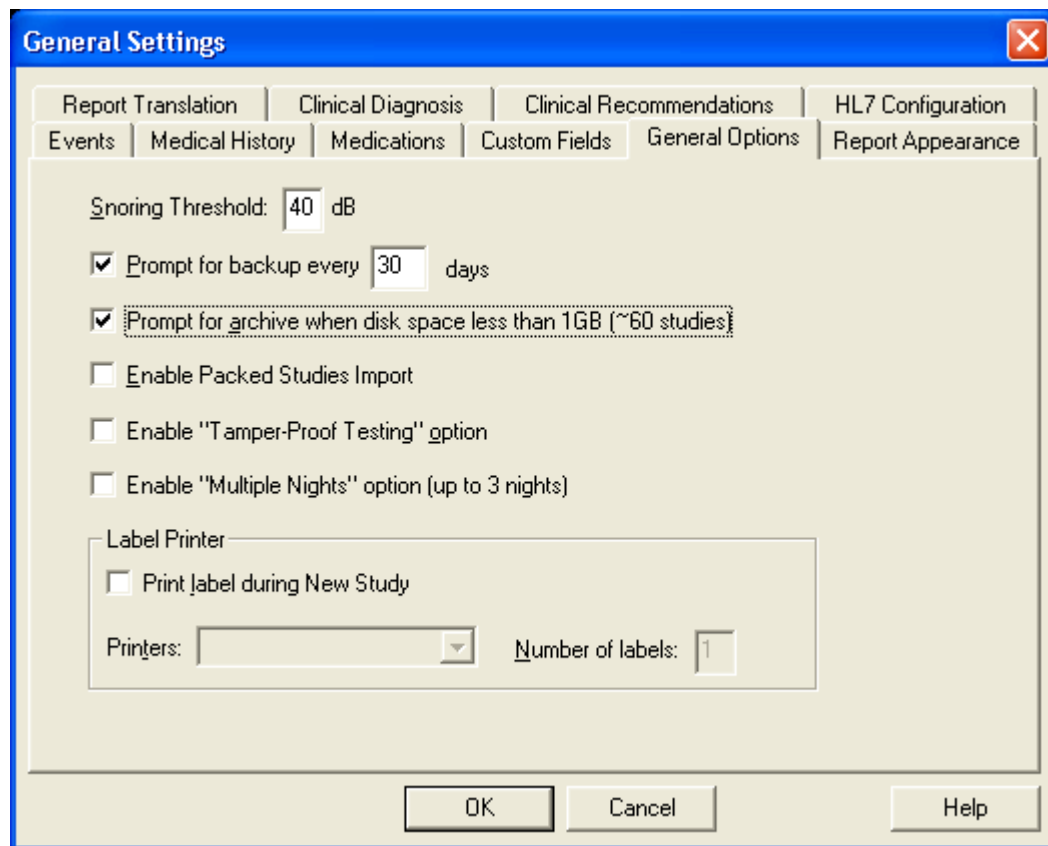



Figure 33 - General Settings Dialog Box – General Options Tab

- Select snoring threshold to be used in calculating snoring statistics (3rd page of report) – used only in non-USA version.
- Check “Prompt for backup every ...” and set the numbers of days to get a reminder message after the last backup of the database was performed.
- Check “Prompt for archive when disk space ...” to get an alert message when available disk space is lower than 1GB.
- Check “Enable Packed Studies Import” if you have access to packed studies from ftp uploads. By enabling this option you can import studies that were uploaded by ftp by selecting Tools>Import Packed studies option from the main menu.
- **For WP200 only:** Enable "Tamper-Proof Testing" if you want to use the Patient Identification Bracelet. By enabling this option you can select to use the bracelet while preparing a New study (see Preparing a New Study).
- **For WP200 only:** Check “Enable Multiple Nights” option if you want to enable the Watch-PAT200 recording up to 3 nights in a row while preparing a New study (see Preparing a New Study).

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	<p style="text-align: center;">Note</p> <p>The "Enable Tamper-Proof Testing" and "Enable Multiple Nights" options are available only when the WP200 internal S/W is version 2.2182 and higher.</p>
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- Check "Print label during New Study" and set the label Printer and the number of labels if you wish to have labels automatically printed when you prepare "New Study Details". This feature will work only with pre-defined label printers. The printers must print at 3 secs/label at a minimum and must be defined by Itamar Medical. The information printed on the label (2x5 cm) will include the following fields: Patient ID, Patient First and Last name, Date of Compact Flash preparation and Coverage (field that may be used for additional data such as device #, etc.). The labels may be attached to WP100 or WP200 suitcases as to provide easy identification of the designated patient after the WP100 or WP200 devices have been initialized with the patient details.

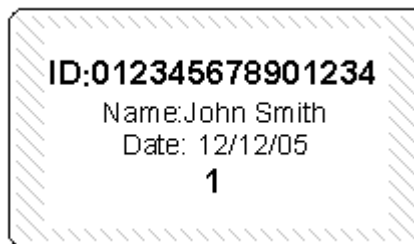



Figure 34 – Label example

	<p style="text-align: center;">Note</p> <p>Contact Itamar Medical for a list of the supported label printers.</p>
---	--

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3.4.6 Setup>General Settings>Report Appearance

Used to change the basic Report appearance, adding a logo, affiliation, header and footer.

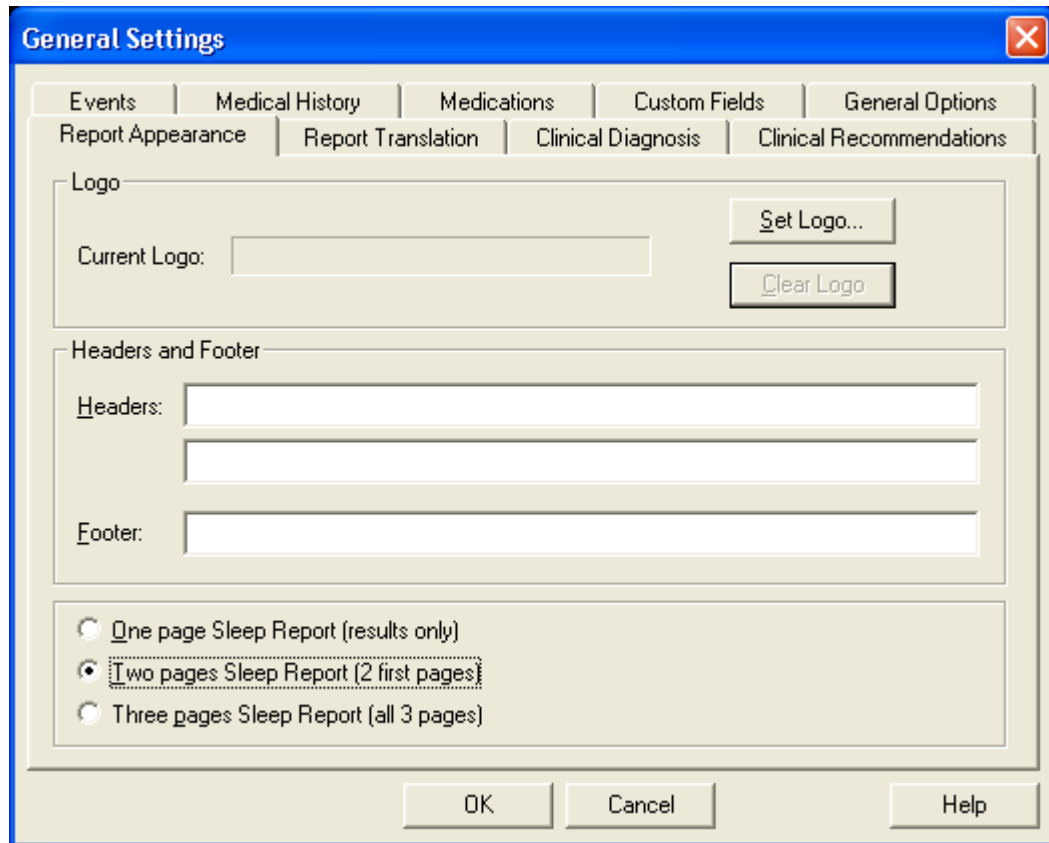


Figure 35 - General Settings Dialog Box – Report Appearance Tab

To add a logo to the sleep report:

- Click the **Set Logo...** to browse for the desired logo file. File may be in bitmap (BMP extension) or JPEG (JPG or JPEG extensions) formats. Highlight the logo file and click **Open** to add the icon. Note that actual Icon size in the report does not exceed 140X100 pixels, therefore larger images will be resized for proper printing.
- To clear the selected logo click **Clear Logo**.

To add a header/footer to the sleep report:

- Type in the desired header text in the Headers field.
- Type in the desired footer text in the Footer Field.

To set the number of pages of the Sleep Report:

- Select "One page Sleep Report" to see the results (statistics and signals) page.

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- Select "Two pages Sleep Report" (default) to see patient, physician and study information in addition to the "One page Sleep Report".
- Select "Three pages Sleep Report" to see sleep/wake states, sleep stages and respiratory indices charts in addition to "Two pages Sleep Report".

3.4.7 Setup>General Settings>Report Translation

Used to change the sleep report headings.

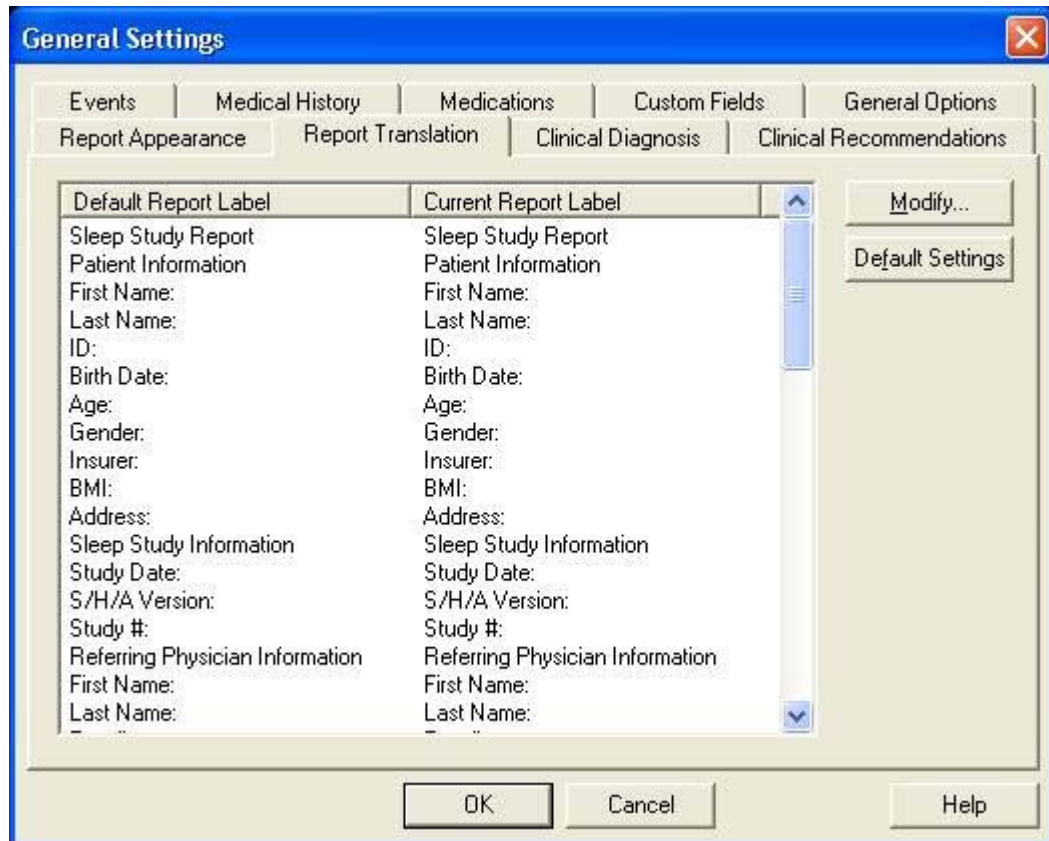



Figure 36 - General Settings Dialog Box – Report Translation Tab

To translate report headings to a different language:

- All report field labels may be changed by selecting the desired report field and clicking **Modify....** In the dialog box that opens you can type the new text to be used in the reports.
- Click **Default Settings** to revert to the default text for all report field labels.

	<p style="text-align: center;">Note</p> <p>Clicking the Default Settings will revert to default settings losing all user defined report labels</p>
---	--

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3.4.8 Setup>General Settings>Clinical Diagnosis

To add a Clinical Diagnosis to the list:

- Insert Clinical Diagnosis name in the 'Add to Clinical Diagnosis' text box. The **Add** button becomes enabled.
- Click **Add**.


To modify a Clinical Diagnosis:

- Click on the listed Clinical Diagnosis.
- Click **Modify**. The Modify dialog box opens with the selected Clinical Diagnosis name.
- Type in the change requested.

To remove a Clinical Diagnosis from the list:

- Click on the listed Clinical Diagnosis.
- Click **Remove**.

Default Settings reverts to the default empty list.

	<p style="text-align: center;">Note</p> <p>Clicking the Default Settings will revert to empty settings losing all user defined setting</p>
--	--

3.4.9 Setup>General Settings>Clinical Recommendations

To add a Clinical Recommendations to the list:


- Insert Clinical Recommendations name in the 'Add to Clinical Recommendation' text box. The **Add** button becomes enabled.
- Click **Add**.

To modify a Clinical Recommendation:

- Click on the listed Clinical Recommendations.
- Click **Modify**. The Modify dialog box opens with the selected Clinical Recommendations name.
- Type in the change requested.

To remove a Clinical Recommendation from the list:

- Click on the listed Clinical Recommendations.
- Click **Remove**.


	<p style="text-align: center;">Note</p> <p>Clicking the Default Settings will revert to empty settings losing all user defined setting.</p>
---	---

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4 Using zzzPAT

4.1 Preparing a New Study

Preparing the Patient file is a mandatory stage in the preparation of the WP100 or WP200 devices for a sleep study. Before proceeding, make sure that the Compact Flash reader drive was defined as described in Section 2.7.

	<p style="text-align: center;">Warning</p> <p>For WP100 only: Use only Itamar provided Compact Flash cards. The Compact Flash cards used by the WP100 have a special format. Compact Flash Cards with regular format will not work and their use will result in a failed test! All references to “Compact Flash cards” in this user manual, refer to Itamar supplied Compact Flash Cards only.</p>
---	--

4.1.1 Launching zzzPAT

- Launch ‘zzzPAT’ by clicking the zzzPAT icon  on your desktop or navigate through: **Start>Programs>zzzPAT>zzzPAT**.
- If the zzzPAT icon  is launched the following login dialog opens:

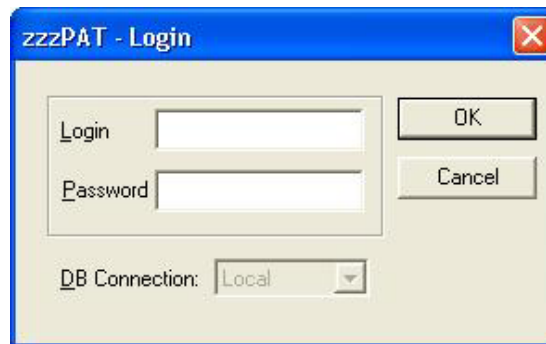




Figure 37 - Login Dialog Box

- Enter Login and Password. When a Shared Access mode is installed, the login screen allows the user to choose to which database the zzzPAT will connect.

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	<p style="text-align: center;">Note</p> <p>In Shared Access mode it is highly recommended to always connect to the Shared database - this will ensure all data is stored in one central location allowing future retrieval from all connected stations. Local database should be selected only if network access is not available, or for special purposes (training, travel etc...).</p>
---	--

	<p style="text-align: center;">Note</p> <p>In Shared Access mode, if data was stored on the local database, it is recommended to export the data into the Shared Access database as soon as practical.</p>
---	---

- If applicable, select the desired database to connect to. Local database should be selected only if network access is not available, or for special purposes (training, travel etc...).
- Enter your login name and password and click **OK** to continue.

4.1.2 Preparing a New Study

For WP100 only:

- Make sure a Compact Flash card is in the Compact Flash reader and connected to the PC with the zzzPAT software.
- Click **File>New Study Details** in zzzPAT, or click the 'New Study' icon  in the tool bar.
- The 'New Study' dialog box appears:

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New Study

Patient

ID: (Mandatory)

First Name: Last Name:

Date of Birth: / / Age: Gender: ☐ Male ☐ Female

Height: ' " Weight: lb.

Neck Circ.: " Epworth:

Demographics... Clinical Data...

Physician

License:

First Name: Last Name:

Demographics...

Study

Coverage: Payment Code: More...


Time Zone: GMT+2:00

Save To USB
Clear Page
Read From USB
Set USB Drive...
Exit

USB Drive: F: Ready for prepare New Study.
DB Connection: Shared

Figure 38 - New Study Dialog Box for WP100

For WP200 only:

- Make sure the device is connected to the PC with the zzzPAT software using the USB cable.
- Click **File>New Study Details** in zzzPAT, or click the 'New Study' icon  in the tool bar.
- The 'New Study' dialog box appears:

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New Study

Patient

ID: (Mandatory)

First Name: Last Name:

Date of Birth: / / Age: Gender: ☐ Male ☐ Female

Height: ' " Weight: lb.

Neck Circ.: " Epworth:

Demographics... Clinical Data...

Physician

License:

First Name: Last Name:

Demographics...

Study

Coverage: Payment Code: More...

Time Zone: GMT+2:00

☐ Study with Tamper-Proof Testing

☐ Multiple Nights (up to 3 nights)

☒ Synchronize WP200 clock with PC clock while 'Saving to USB'

WP200 clock: 10/21/2009 19:30

USB Drive: F: Data not loaded (load first).

DB Connection: Shared




Save To USB
Clear Page
Read From USB
Set USB Drive...
Exit

Figure 39 - New Study Dialog Box for WP200

- Fill the mandatory Patient ID in the **Patient** fields.
- Insert any additional information if needed, the rest of the fields are optional.
- Select "Study with Tamper-Proof Testing" if you want to use the Patient Identification Bracelet. By enabling this option you can use the bracelet in order to verify that the identified patient is indeed the one sleeping with the device (see Tamper-Proof testing in Watch-PAT200 Operation Manual). This option is shown only if the feature is enabled in Setup>General Settings>General Options.
- Select "Multiple Nights" option in order to run up to 3 nights with the same WP200 device (see Multi-night study in Watch-PAT200 Operation Manual). This option is shown only if the feature is enabled in Setup>General Settings>General Options.

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- Click the **Save to USB** button.

	<p style="text-align: center;">Note</p> <p>If the Patient ID field was left unfilled, a message will be displayed requesting the need to be filled. Fill in the missing information and press the Save to USB button again.</p>
	<p style="text-align: center;">Note</p> <p>The units used for weight and height in the 'New Study' dialog box are defined by the regional settings of the PC.</p>
	<p style="text-align: center;">Note</p> <p>The Epworth Score is used to determine the level of daytime sleepiness. An Epworth Sleepiness Scale Questionnaire can be found in the Misc folder under the zzzPAT Installation folder (the default is C:\Program Files\Itamar medical\zzzPAT\Misc).</p>

If the Compact Flash card/WP200 contains data (either a night study that has not been loaded to the zzzPAT Database or new patient data that has been prepared but not used in a study), the following dialog box opens:

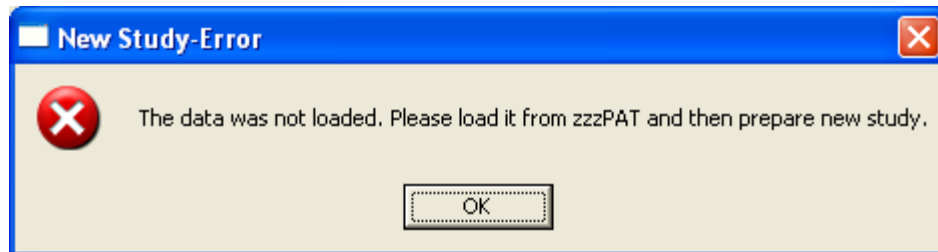


Figure 40 - Compact Flash Card/WP200 Not Loaded Dialog Box

- After saving the patient information to the Compact Flash card/WP200 the following message appears:

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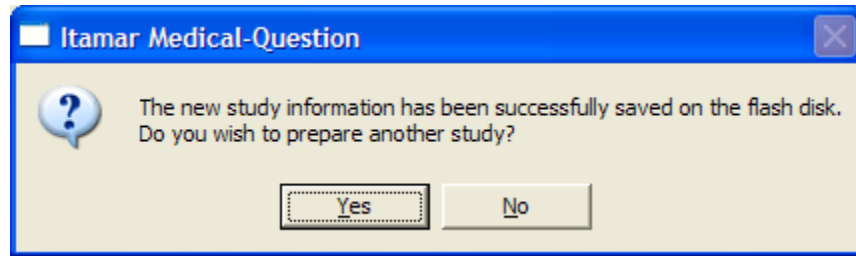


Figure 41 - New Study Termination Question

Click **Yes** - if you wish to prepare additional Compact Flash cards.
Click **No** - if you wish to exit the 'New Study' dialog box.

- **For WP100 only:** Take the Compact Flash card from the Compact Flash reader and insert it into the appropriate compartment in the WP100. (Refer to the WP100 user manual).
- **For WP200 only:** Disconnect the USB cable from the WP200 device.

4.1.3 New Study screen features

Besides the main screen fields required for preparing a new study, there are additional fields that allow thorough documentation of the patient's past and current medical condition. In addition, zzzPAT enables you to load patient details from previous studies. Other features in this screen enable organizing the studies into groups using categories of your choice.

4.1.3.1 Synchronizing the WP100 device clock with the zzzPAT software

The internal clock of the WP100 device needs to be set correctly in order for the Study Date/Time to appear correctly after loading a study in zzzPAT.

Since zzzPAT version 3.0 all WP100 devices are delivered from Itamar Medical having the internal clock set to GMT (Greenwich Mean Time).

The "Time Zone" field in "New Study" screen contains the offset in hours that is added or subtracted to the Study Date/Time read from the WP100 device.


- If the WP100 device clock is set to GMT - this offset equals to the difference in hours between the computer's local time and GMT
- If the WP100 device clock is set to local time - this offset equals to zero (select GMT on the pull down menu)


To adjust for daylight savings or if you notice a discrepancy in hours between the actual Study Date/Time and the one obtained in zzzPAT, you can change the "Time Zone" field in "New Study" screen in order to compensate for the discrepancy:


- If zzzPAT date/time is later than the actual Study Date/Time - decrease the "Time Zone"

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- If zzzPAT date/time is earlier than the actual Study Date/Time - increase the "Time Zone"

	<p style="text-align: center;">Note</p> <p>You do not need to set the "Time Zone" field each time you prepare a New Study. The software "remembers" the last "Time Zone" used.</p>
---	---

	<p style="text-align: center;">Note</p> <p>The local GMT offset can be found in Start>Settings>Control Panel>Date and Time>Time Zone.</p>
---	---

	<p style="text-align: center;">Note</p> <p>When you run Watch-PAT Monitor (version 2.1.45.1 and earlier) with WP100 devices whose clock is set to GMT the Date/Time test will fail.</p> <p>As long as the difference between the WP100 device clock and the computer clock is equal to the GMT offset, the device clock should be left unchanged.</p>
---	--

4.1.3.2 Synchronizing the WP200 device clock with the zzzPAT software

Select the "Synchronize WP200 clock with PC clock while 'Saving to USB'" option while preparing new study if the WP200 device clock needs too be set (see Figure 39).

4.1.3.3 Documenting additional information

To add demographic information:

- Click the **Demographics** button (see Figure 38). The following dialog box will open:

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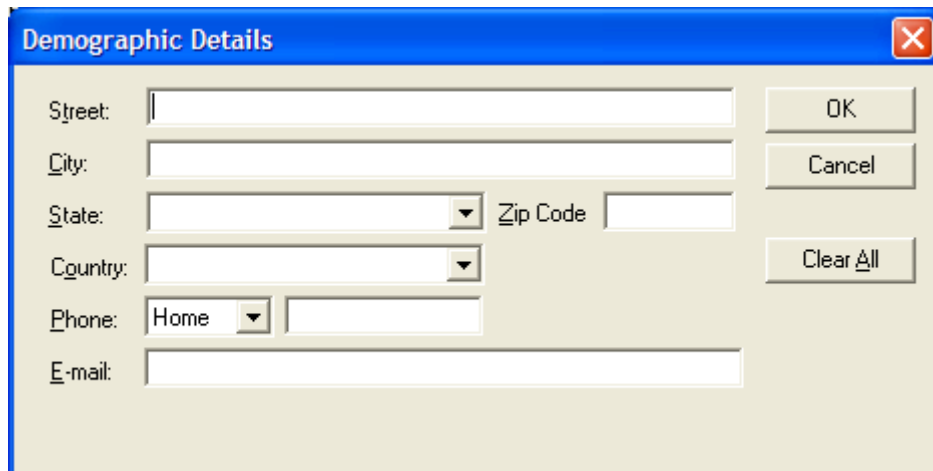
A screenshot of a software dialog box titled "Demographic Details". The dialog box has a blue title bar with a close button (X) in the top right corner. The main area is light beige and contains several input fields and buttons. On the left, there are labels for "Street:", "City:", "State:", "Country:", "Phone:", and "E-mail:". The "Street:" label is followed by a text input field. The "City:" label is followed by a text input field. The "State:" label is followed by a dropdown menu. The "Country:" label is followed by a dropdown menu. The "Phone:" label is followed by a dropdown menu with "Home" selected and a text input field. The "E-mail:" label is followed by a text input field. To the right of the "State:" and "Country:" dropdowns is a label "Zip Code" followed by a text input field. On the right side of the dialog box, there are three buttons: "OK", "Cancel", and "Clear All".

Figure 42 - Demographic Details Dialog box

- Insert the information into the appropriate fields and click **OK** to save.

To add optional clinical information:

- Click the **Clinical Data** button. The following dialog box opens:

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Clinical Data

Medical History

List of available medical conditions:

- Acrocyanosis
- Acromegaly, Micrognathia
- Buerger's disease
- Cheyne-Stokes breathing
- Chronic pulmonary disease
- Chronic/recurrent allergic rhinitis/sinusitis/de
- Congenital heart disease
- Coronary artery disease
- Diabetes Mellitus
- Epilepsy
- Esophageal reflux
- Females only: menstruation

(Please double click on the list to add an item to the Medical History box)

Patient's medical conditions:

Medications

List of available medications:

- ACE inhibitors
- Alpha-reductase inhibitors (for Tx. Of B.P.H.)
- Amphetamines
- Anti-hypersensitive alpha-blockers
- Anti-migrainotic Ergot alkaloids
- Anti-Parkinsonian agents
- Anti-psychotic or anti-depressive drugs
- Beta-blockers
- Calcium channel blockers
- Dopaminergic drugs
- Long acting nitrates
- M&D stimulant or inhibitors

(Please double click on the list to add an item to the Medications box)

OK

Cancel

Clear All

Figure 43 - Patient Clinical Data Dialog box

- Double click on the relevant items listed on the left, to add them to the Patient information or add information in free text.
- After adding the selected data click **OK** to save.


To remove an item from your selection:

- Highlight the item you want to delete.
- Hit delete key or right click and choose 'Delete' from the pop-up menu.
- Click **OK** to continue.


4.1.3.4 Retrieving patient information from previous studies

This feature allows retrieving patient information from previous studies into current 'New Study' dialog box. In addition it enables viewing the list of all patients in the zzzPAT database.


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	<p style="text-align: center;">Note</p> <p>If a patient has more than one study, only the latest patient details inserted will be displayed</p>
---	--

To view a list of all the patients in the zzzPAT database:

- In the 'New Study' dialog box (Figure 38), leave the fields: 'patient ID', 'first name' and 'last name' empty.
- Click , the 'Search Results' dialog box will open with a list of all the patients in the zzzPAT database.
- Select the study you need and click **OK**. The patient's information will be retrieved into the 'New Study' dialog box.

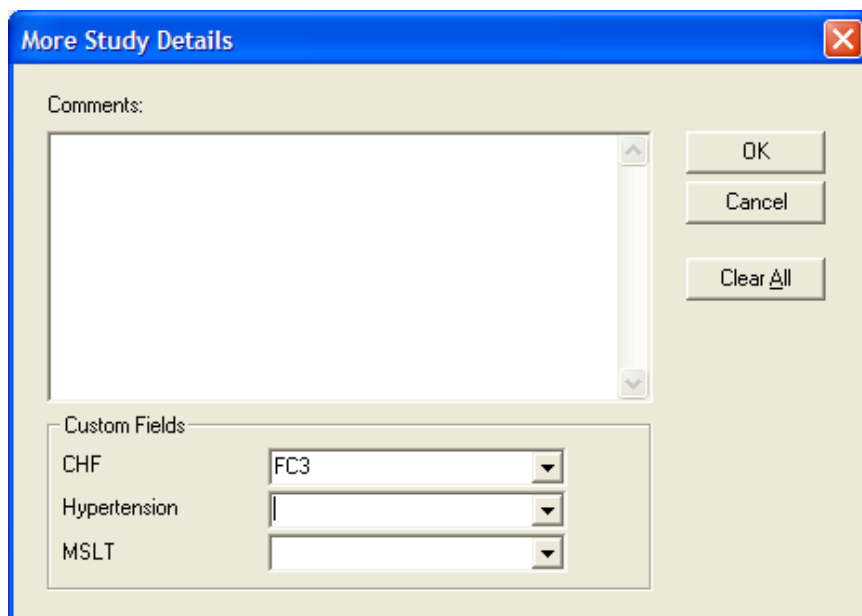
To view patients by selected categories:

- Enter patient ID, first or last name into the 'New Study' dialog box.
- Click , the 'Search Results' dialog box will open with a list of patients that will match the criteria inserted above.
- Select the patient you need and click **OK**. The patient's information will be retrieved into the 'New Study' dialog box.

4.1.3.5 Classifying the patients by special categories or groups

To assign a study to a group or category:

- Click the **More** button in the **Study (optional)** section of the 'New Study' dialog box. The following dialog box will open:




The 'More Study Details' dialog box features a blue title bar with a close button. It contains a 'Comments:' label above a large text area. To the right of the text area are three buttons: 'OK', 'Cancel', and 'Clear All'. Below the text area is a section titled 'Custom Fields' containing three rows, each with a label and a dropdown menu: 'CHF' with 'FC3' selected, 'Hypertension', and 'MSLT'.


Figure 44 - More Study Details Dialog box

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- You can enter free text in the 'Comments' field and select an existing study group from the list you previously prepared in the 'Study Custom Fields' or insert free text into the fields of the **Custom Fields** section.

	<p style="text-align: center;">Note</p> <p>Up to three 'Custom Fields' can be defined and named by the user. If Study Custom Fields' are not defined, they will appear in the 'More Study Details' Dialog box as read only (Figure 44). To define 'Custom Fields' see section 3.4.4.</p>
---	---

4.1.3.6 Reviewing and editing information stored on a Compact Flash Card

	<p style="text-align: center;">Warning</p> <p>It is possible to change information on a Compact Flash card only before the recording session. Changing information after a recording session will erase the recorded information on the Compact Flash card.</p>
---	--

- Insert the Compact Flash card into the Compact Flash reader.
- Open 'New Study' application. Click **Read From USB** button.
- If the information does not need to be edited, click **Exit**.
- Make any necessary changes and click **Save to Flash**.


	<p style="text-align: center;">Note</p> <p>Study details, including patient information, can be viewed and modified after the study is loaded from the Compact Flash card to the zzzPAT database. See Section 4.2.7 for more details.</p>
---	--

4.2 Managing Patient Studies

After a WP100 sleep study, remove the Compact Flash card from the WP100 and insert it into the zzzPAT Compact Flash reader. The recorded digital data along with patient information are loaded into the zzzPAT database. The recorded data is automatically analyzed. The user can subsequently review, edit, add Diagnosis and Recommendations and produce a Sleep Report. Previously loaded studies can be opened and reviewed.

The remainder of this section assumes zzzPAT is running.

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	<p style="text-align: center;">Note</p> <p>When working in Shared Access mode it is important to login to the correct database in which the data needs to be stored. Typically that should be the Shared database, however if data was stored locally, local login may be required.</p>
---	--

4.2.1 File>New Study Details

Prepares the Patient file on the WP100 Compact Flash card for a sleep study (Section 3).

4.2.2 File>Load Study and Analyze

This command loads the sleep study data from the Compact Flash card and saves it into the zzzPAT database.

While loading the data the message 'Loading Study' (Figure 45) appears on the screen indicating that the data is being transferred from the Compact Flash card to the hard disk and the patient file is saved in the database.

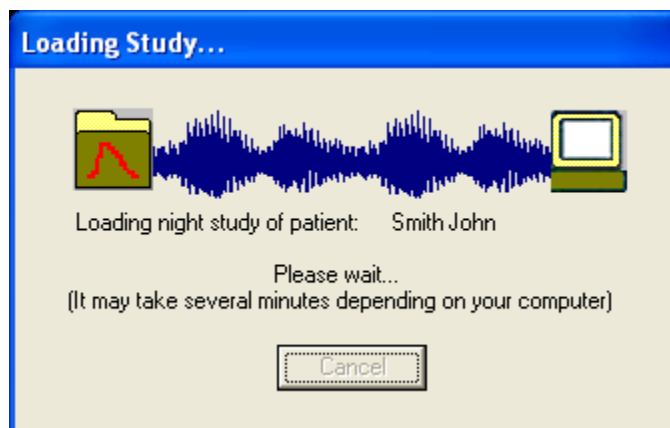



Figure 45 - Loading Study dialog box

At this stage Automatic Analysis is performed and the results are saved in the database. After the Automatic Analysis is completed the results are displayed on screen (see Figure 48). The user has the option to display the "Sleep report" or "Sleep Indices" report box automatically after loading a study (see 3.3.3).

When a multi-night study is loaded all the night studies are loaded automatically and the last loaded study will be displayed. Use the Open Study dialog to open and review all the night studies.

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4.2.3 File>Open Study

Opens studies stored in the zzzPAT database from previously loaded studies (see Figure 46). Double click on a patient and the studies for that patient are listed with the date/time of each study. Double click the  study icon to load and display recorded information on the screen.

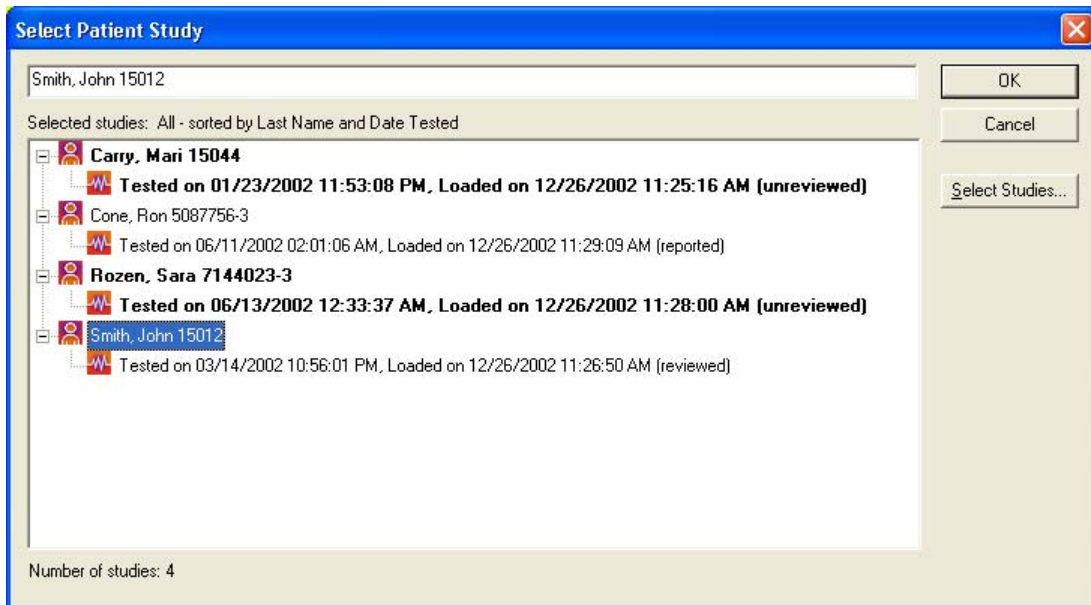
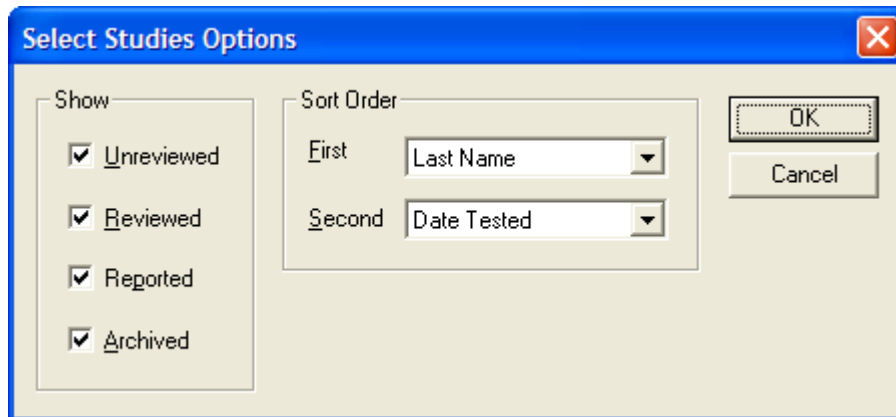


Figure 46 - Select Patient Study dialog box

Select Studies button

Enables the user to define, select and organize the displayed studies in the 'Select Patient Study' dialog box.

- Click **Select Studies**.
The following Dialog box will open:




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Figure 47 - Select studies option

Show section - Each study is associated to one of the following statuses (listed bellow). Checking the boxes to the left of these statuses enables the user to define, according to the following categories, which of the studies from the zzzPAT database will be displayed on the 'Select Patient Study' dialog box:

- | | |
|------------|---|
| Unreviewed | – Study was loaded to zzzPAT and automatic analysis performed on it. |
| Reviewed | – User modified events, entered Diagnosis or Recommendations, saved study results or produced a sleep report. |
| Reported | – User selected the 'Set as Reported' option in the 'Clinical Diagnosis' dialog box. This study cannot be modified and no additional information can be inserted into the report. |
| Archived | – Study was extracted and removed from the database to an archive out-side the zzzPAT database. These studies cannot be reviewed unless retrieved back into the database first. |

	<p>Note</p> <p>The usual cycle of a study is: Unreviewed → Reviewed → Reported → Archived</p>
---	--

Sort Order section - Enables the user to define the order by which the studies are displayed. It is possible to display the studies by ID, last name, date of study, date file loaded and additional user inserted criteria.

- | | |
|----------------------|---|
| 'First' order field | – Contains system predefined criteria and user defined criteria inserted in 'Define Study custom Field' (see 4.1.3.5) |
| 'Second' order field | – Contains only system predefined criteria. |

4.2.4 File>Save Study Results

Saves the patient study results (events) currently being viewed without closing zzzPAT, and sets the study as reviewed. This feature is important when Respiratory events are edited (added or deleted) and the new events need to be saved for future zzzPAT sessions.

4.2.5 File>Close Study

Closes the patient study currently being viewed without closing zzzPAT.

4.2.6 File>Exit

Closes both the patient study being viewed and the zzzPAT.

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4.2.7 Edit>Study Details

Opens the 'View Study Details' dialog box with current patient information. This information can be edited by clicking the **Edit** button. Authorization users can change the patient ID only once.

4.3 The Display Screen

The main screen displays the WP100 or WP200 recording waveforms with the events that were detected by the automatic analysis. The traces are displayed synchronized to a uniform time base.

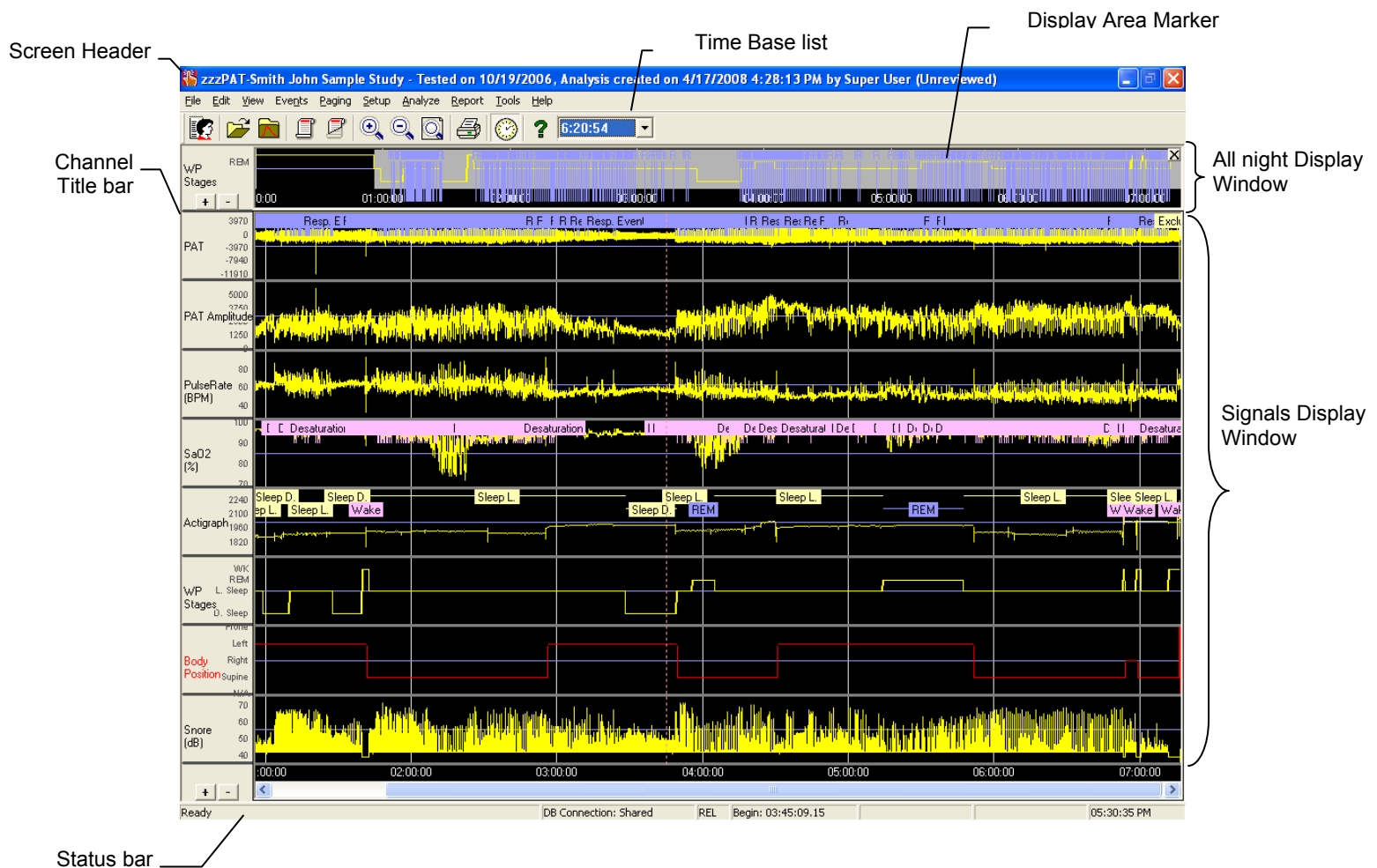


Figure 48 - zzzPAT display screen

The 'Screen Header' consists of 'zzzPAT', patient's name, ID number, Analysis status, date and time and the zzzPAT user's name.

Events determined by the Automatic Analysis are displayed on the 'Signals Display Window'.

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Placing the mouse cursor on an event pops up a tool-tip that contains:

- Event name
- Event source (Analysis or User)
- Start time
- Duration

4.3.1 The All Night Window

It is possible to view any channel you select in an 'All Night Window' display even if you change the time base for viewing all the channels of the study.

- To display the All-Night window, navigate through **View>All Night Window**, check the 'All Night' option.
Or **View>Channels**,
The following dialog box will open:

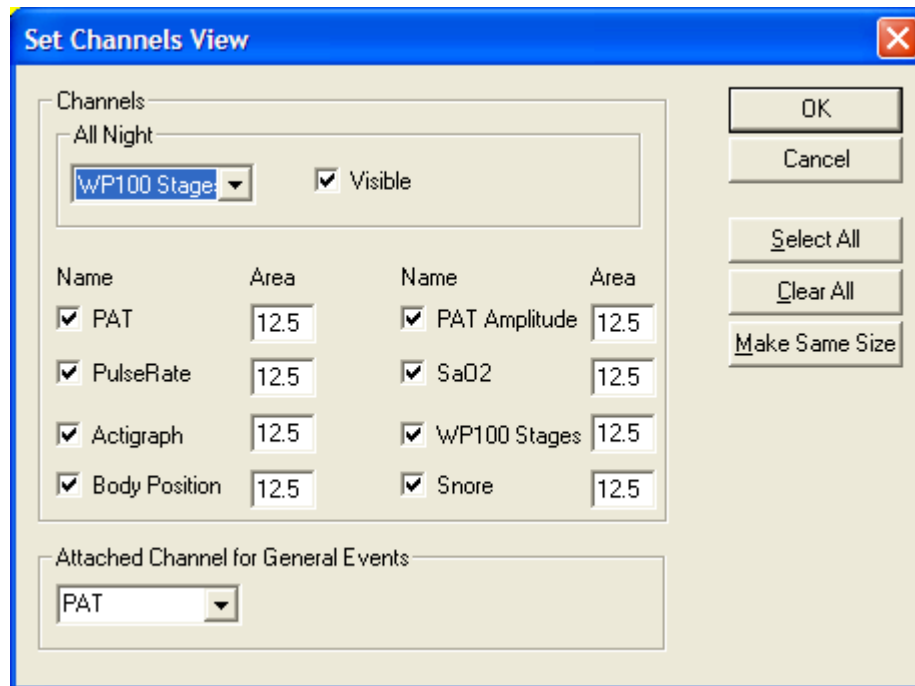


Figure 49 - Selecting the All night Window

- Check the box to the left of 'Visible' in the **All Night** section.
- Select the channel you wish to display in the 'All Night Window'.

To remove the 'All Night Window':

- Use the two options mentioned above or right click on the 'All Night Window' title window (left side of the screen), select 'Remove from View'.

'All Night Window' features:

- The 'Display Area Marker' that appears as a highlighted rectangle in the 'All Night Window' (See Figure 48), is the section being viewed in the 'Signals Display Window'.

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- It is possible to navigate through the recorded data through the 'All Night Window' by clicking on a spot on the 'All-Night' window, or by dragging the highlighted rectangle.
- When in the 'All Night Window' display, clicking the mouse right-button opens the following pop-up menu:



Figure 50 - All Night pop-up Menu

- | | | |
|-------------------------|---|---|
| Fit to Window | – | Auto fits the All Night window's signal so it is displayed in about 80% of the window's height. |
| Invert Data | – | Inverts the y-Scale and signal of the All Night window. |
| Show Channel Events | – | Displays channel events in the All Night window. |
| Show Respiratory Events | – | Displays respiratory events in the All Night window. |
| Grid On/Off | – | Toggles the grid in the All Night window. |
| Properties | – | Opens up the 'Signal Properties - All Night' dialog box (see Figure 51). |

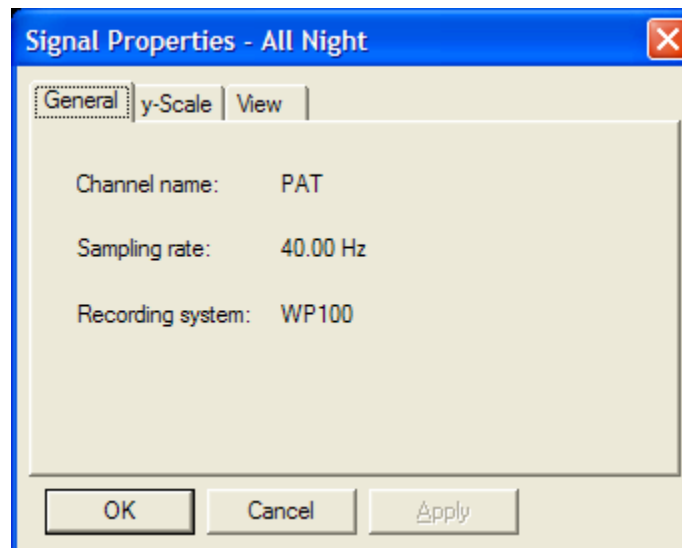


Figure 51 - Signal Properties – All Night window

Right clicking the mouse on the 'All Night' channel Title to the left of the All Night display opens a pop-up menu with the following options:

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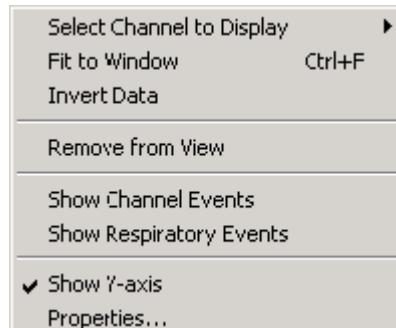


Figure 52 - All Night pop-up menu

Select Channel to Display	–	Allows the user to choose which channel will be displayed in the 'All Night Display Window'.
Fit to window	–	Auto fits the channel's signal so it occupies 80% of the window's height.
Invert Data	–	Inverts the y-Scale and signal of the channel.
Remove from View	–	Removes the 'All Night Window' from the main screen.
Show Channel Events	–	Allows option of showing or not showing all the events on the All Night channel.
Show Respiratory Events	–	Allows option of showing or not showing only respiratory events on the All Night channel.
Show Y-axis	–	Shows the Y-axis for the selected channel.
Properties	–	Opens up a dialog box with the General, Y-Scale and View properties of the channel.

4.3.2 Signals Display Window

The signals display window is located under the 'All Night' window. It displays the channels that are selected in the **View>Channels** menu.

4.3.3 Channel Title Bar

'The Channel Title Bar' on the left of the screen shows the titles of the channels being displayed and the y-Scale of each channel.

4.3.4 The Active Channel

Clicking on a channel or a channel title activates that channel (the color of the activated signal and titles will change).

A right-button click on a Channel title activates the channel and opens a pop-up menu with the following options:

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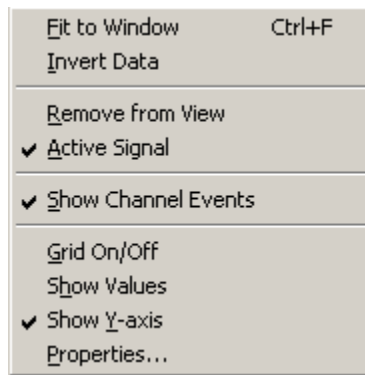


Figure 53 - Active channel pop-up menu

Fit to window	– Auto fits the active channel's signal so it occupies about 80% of the window's height.
Invert Data	– Inverts the y-Scale and signal of the Active channel.
Remove from View	– Removes the currently active channel from the screen.
Active Signal	– Allows deactivating the signal.
Show Channel Events	– Allows option of showing or not showing the events in the Active channel.
Grid On/Off	– Toggles the grid in the Active channel.
Show Values	– Shows the values for each data point on the Active channel (effective only under maximum zoom).
Show Y-axis	– Shows the Y-axis values for the Active channel.
Properties	– Opens up a dialog box with the General, y-Scale and View properties of the Active channel.

4.3.5 Status Bar

The Status Bar at the bottom of the screen contains the following information:

- Database connection (Shared or Local)
- Real Time Clock
- Highlighted segment start time
- Highlighted segment end time
- Duration
- Time mode (REL/ABS)

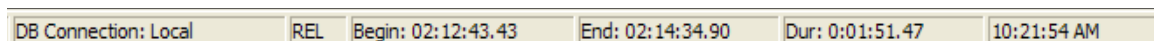


Figure 54 - zzzPAT screen Status Bar

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4.4 Signal Display Options

4.4.1 View>Channels

Opens the following dialog box:

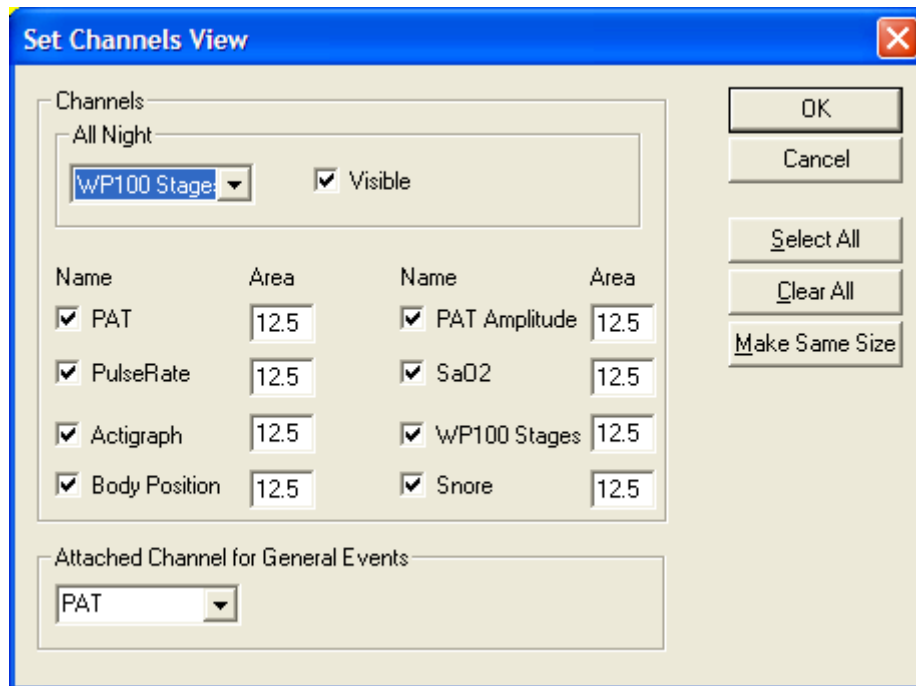


Figure 55 - Set Channels View Dialog Box

The **All Night** section is used to enable/disable the 'All Night display' and to select the channel for it.

Checking the boxes by the channel names defines the channels displayed on the zzzPAT screen.

The value entered into the 'Area' fields determines the channel's screen display relative size. The total sum of the values in the Area fields should be 100. Clicking the **Make Same Size** button rescales all channels to the same size.

The **Attached Channel for General Events** section is used to set the channel on which the general events are displayed. General events are events generated by the automatic analysis of the zzzPAT.

4.4.2 View>Set y-Scale

Opens the 'Set y-Scale' dialog box.

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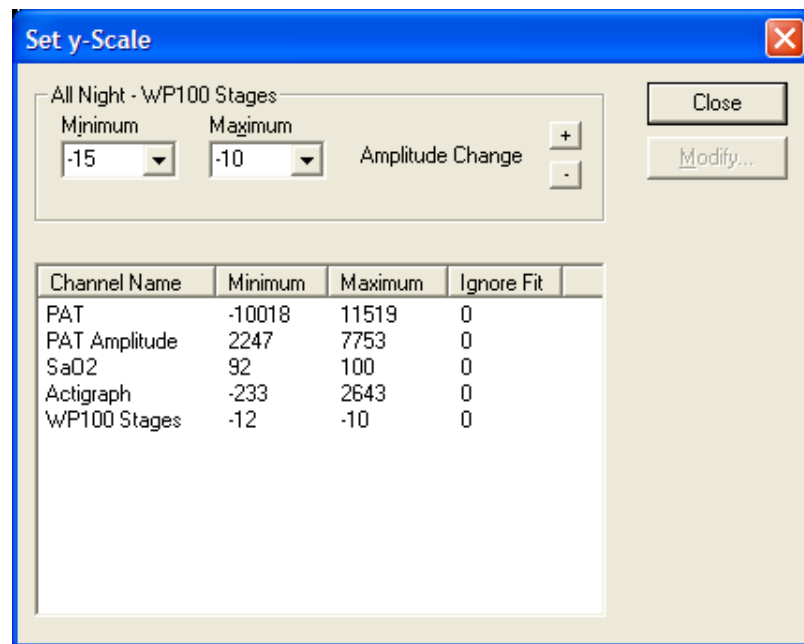


Figure 56 - Set y-Scale dialog box.

The **All Night** section allows editing the 'y-scale' for the 'All Night' channel.

To edit the 'y-Scale' of all other channels:

- Mark the channel on the 'Set y-Scale' dialog box.
- Click **Modify**. The following dialog box will open:

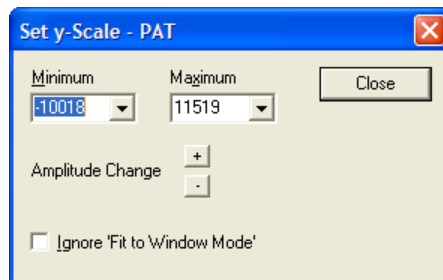




Figure 57 - Set y-Scale – per channel dialog box

- Select minimum/maximum ranges for the y-Scale or control the channel's gain with .
- Define whether to ignore 'Fit to Window Mode'. (See section 4.4.6).

To edit the y-Scale using the zzzPAT screen:

- Activate a channel by clicking anywhere on it.
- Click on the  buttons at the bottom of the channels Title Bar.

To raise or lower the range scale of a channel:

- Left click on the channel title bar and drag the scale range numbers.

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To zoom on a specific range of the channel:

- Right click and drag to the desired range.

4.4.3 View>Time Base

Enables to select the time base by which the study is viewed on the zzzPAT screen. It is also possible to select the time base by using the 'Time Base Drop Down Menu' in the zzzPAT tool bar.

4.4.4 View>Activate Channel Fit to Window

Sets the signals display to automatically take 80% of the selected signal's window height. The size of the signal will automatically adjust to take no more than 80% of the vertical axis of its display.

Automatic 'Fit to Window' mode is applicable only for the section being viewed on the screen. It will be disabled when viewing the study by paging (using the Page Up and Page Down keys on the keyboard) or when scrolling (using the Right Arrow and Left Arrow keys on the keyboard).

4.4.5 View >All Night Channel Fit to Window

Activates the Fit to Window mode on the 'All Night Channel'.

4.4.6 View>Fit To Window Mode

This command activates a 'Fit To Window' mode on all the displayed channels. In this mode the size of the signal will automatically adjust to take no more than 80% of the vertical axis of its display.


All the channels will remain in 'Fit to Window' mode when viewing the study by paging (using the Page Up and Page Down keys on the keyboard) or when scrolling (using the Right Arrow and Left Arrow keys on the keyboard).

Note: It is recommended to disable the 'Fit to Window' Mode on the actigraphy channel. For instructions see section 4.4.2.

4.4.7 View>Grid On/Off

Displays the grid lines of the channel values. User may enable or disable the Grid On/Off feature for a specific channel by right clicking the mouse on the highlighted channel.

4.4.8 View>Relative Time


Choosing this option or clicking  on zzzPAT toolbar toggles the time mode of the study being viewed between Absolute Time mode and Relative Time mode.

In Relative Time mode the beginning of the study is always defined as 00:00:00 on the x-scale of the zzzPAT screen and the time is measured from the beginning of the study.

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In Absolute Time mode the absolute time appears on the x-scale of the zzzPAT screen; i.e. the time registered by the WP100 or WP200 device.


4.4.9 View>Zoom In

To enable this option, highlight a section of the waveform by clicking and dragging the mouse. The option **View>Zoom In** and the corresponding toolbar button  become enabled.

Activating the 'Zoom In' option modifies the Time Base to fit the highlighted segment into the entire width of the Signals Display Window (Note that the Time Base window and the Status bar details are updated automatically).


When the time base is one second, the zoom in option is disabled.

4.4.10 View>Zoom Out

View>Zoom Out and corresponding toolbar button  are enabled when the current view is zoomed in.

Activating this option returns the view back to the previous zoom magnitude.

4.4.11 View>Zoom Original

View>Zoom Original and corresponding toolbar button  are enabled when current view is zoomed in. This option returns the view back to the original time scale.

4.4.12 View>All Night Window

Enable/disable the All Night Window (See section 4.3.1).

4.5 Review, Analysis and Report Study

4.5.1 Data Analysis

The zzzPAT software performs an automated analysis of the WP100 or WP200 recorded signals, providing extensive information on the patient's sleep. The analysis provides an evaluation of respiratory events during sleep, oxygen saturation statistics and REM sleep statistics.

4.5.1.1 Generating an Analysis

Recorded study data is automatically analyzed after being loaded from the Compact Flash card. You can also execute automatic data analysis by clicking **Analyze>Reload study and analyze**.

This function reloads the saved study data and executes the automatic analysis. If the user changed the file (adding/deleting/modifying events), these changes will be erased and will not impact the analysis.

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When used on a file that was previously analyzed and saved with an older version of zzzPAT, this function creates a new analysis using the current version of the zzzPAT software.

4.5.1.2 REM Analysis

REM analysis is part of the automatic analysis described above.

Under certain conditions, REM analysis is unable to conclusively determine REM periods from the recorded signals.

When this occurs, the display will include only sleep and wake stages, and in the report the REM statistics section shall be disabled stating "Inconclusive REM Detection".

4.5.2 Event Management

Events marked by automatic analysis are shown in color-shaded boxes. Placing the cursor on an event opens a tool-tip with the following information:

- Event name
- Event created by...(e.g. Automatic analysis or user)
- Start time
- Duration

4.5.3 Edit>Copy

When a signal section is highlighted, the Copy feature is enabled to allow user to copy the desired data either to the clipboard as an image or to files in binary format.

4.5.4 Edit>Undo

'Undo' is enabled only after changing events, enabling the user to undo the last operation.

4.5.5 Edit>Redo

'Redo' is enabled only after using the 'Undo' option, enabling the user to redo the last operation.

4.5.6 Adding events

Respiratory and user defined events can be added to the study by the user.

To add events:

- Mark the place you want to insert the event by clicking on the location with the mouse.
- Right click on the location and select the 'Add Event' command. Or by using the zzzPAT tool bar: **Events>Add Event**.
The 'Add Events' Dialog box will open.

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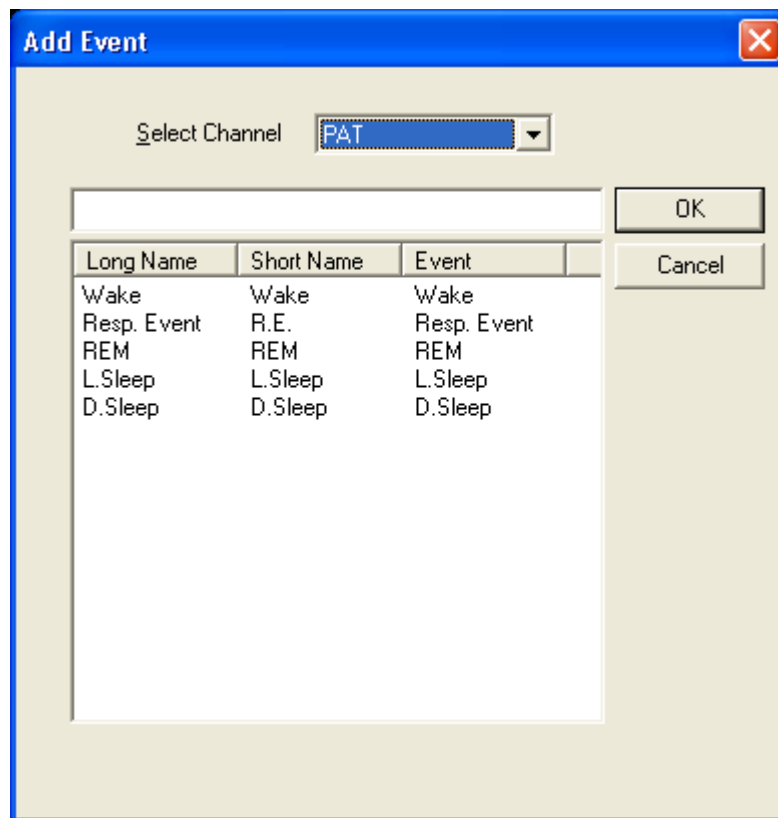


Figure 58: Add Event dialog box

- 'Select Channel' - Allows user to define the channel on which the added event will appear, by default the events will appear on the active channel unless a different channel is selected in the 'Select Channel' field.
- To add event - Double click on the event type in the list of events. Click **OK** to continue.
- It is also possible to add free text events into zzzPAT signal display using the Free Text editing box. This text will appear on the signal as an event but will not appear in the report


The changes in the database are saved by pressing the **Save study results** button.

4.5.7 Deleting an Event

An event can be deleted by right mouse button click on the event and selecting 'Delete Event'.

Only Respiratory and user events can be deleted.

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	<p style="text-align: center;">Note</p> <p>Adding or deleting a respiratory event affects the results in the report.</p>
---	---

4.5.8 Events>GoTo Event

Allows the user to navigate through the study by certain event criteria.
The following event type search options are available:

Previous Event	Ctrl+Left arrow
Next Event	Ctrl+Right arrow
Previous Same Type Event	Shift+Left arrow
Next Same Type Event	Shift+Right arrow
First Event for channel	Ctrl+Home
Last Event for channel	Ctrl+End

Figure 59 - Event Type Search options

4.5.9 Events>Select Event

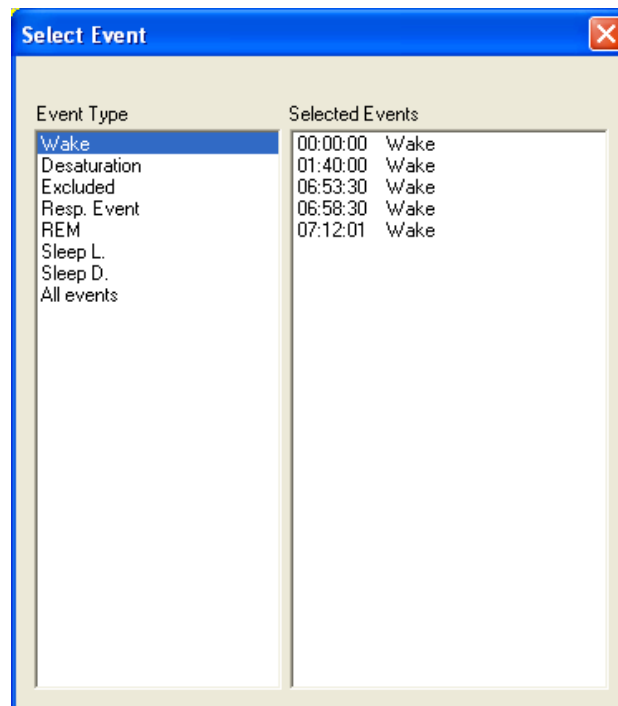


Figure 60 - Select Event dialog box

Enables the user to select a specific event for viewing. All existing events are listed by type and start time. User may select a specific event by clicking on it. The 'Selected

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Events' field in the 'Select Event' window is updated to display the page with the specific event.

4.5.10 Editing Sleep Stages

You are able to manually edit the Sleep stages if you already selected to enable this option (see Setup>General Settings>General Options). In order to edit the sleep stages right click the mouse while on top of the sleep stage and then select a new sleep stage from the "Replace with" menu (see Figure 61)



Figure 61 – Editing sleep stages



4.6 Reports

All reports can be reviewed on screen and printed.

The toolbar in report view mode includes the following items:



Figure 62 - Report Toolbar


- To print a report, click on the printer icon.
- To export a report to a different format, such as pdf, rtf, html, etc., select the export icon .
- User can see how many pages there are in a report and choose which page to view by using the  icons.

4.6.1 Report>Clinical Diagnosis

Allows adding a diagnosis and recommendations to the Sleep Report screen (see Figure 63). The information filled in this screen will appear on the first page of the Sleep Report.

- Sign the report by typing in your name or choosing it from the name menu bar.
- Check the 'Set as Reported' option to show that the current study analysis is final and that the Sleep Report is a final report for this analysis.

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	<p style="text-align: center;">Note</p> <p>Multiple analyses may be associated with a particular study. A new analysis will be created when selecting the 'Analyze>Reload Study and Analyze' option on a study that had been previously 'Set as Reported'.</p>
---	--

Clinical Diagnosis

Medical Information

Medical History

Add

Medications

Add

Comments

Diagnosis

Add

Recommendations

Add

Report Signed By

Super User

☐ Set as Reported



OK

Sleep Report

Cancel

Figure 63 - Clinical Diagnosis dialog box

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	<p style="text-align: center;">Note</p> <p>Once a study is 'Set as Reported' any subsequent change to any of the 'Clinical Diagnosis' dialog fields (Reports>Clinical Diagnosis) will trigger the following warning message:</p> <div data-bbox="532 430 1328 693" style="border: 1px solid blue; padding: 10px; margin: 10px auto; width: fit-content;"> <div style="background-color: #0056b3; color: white; padding: 5px; border-bottom: 1px solid blue;"> zzzPAT-Warning ✕ </div> <div style="padding: 10px;">  <div style="margin-left: 10px;"> <p>The current Analysis is 'Reported', therefore it can not be modified. A new Analysis will be created. Do you wish to continue?</p> <div style="text-align: center; margin-top: 10px;"> <input type="button" value="Yes"/> <input type="button" value="No"/> </div> </div> </div> </div> <p style="text-align: center;">Figure 64 - New Analysis Warning message</p> <p>Click Yes to save a new analysis without overwriting the existing analysis. Click No to cancel the new analysis request.</p>
---	---

4.6.2 Report>Sleep Report

Generates a one, two or three page report that provides a summary of the subject's sleep study according to the settings in Setup>General Settings>Report Appearance section.

The first page of the report (Figure 66) includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page (Figure 67) presents the study results including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), Oxygen Saturation Statistics including the Oxygen Desaturation Index (ODI), mean, maximum and minimum oxygen saturation levels, Oxygen Saturation analysis, Pulse Rate statistics and REM Sleep analysis. It also includes graphical displays of Respiratory Events, Snore and Body Position chart (in case a Snore/Body Position sensor was used), Oxygen Saturation, Pulse Rate, Wake/Light Sleep/Deep Sleep and REM stages.

The third page (Figure 68) presents pie charts of sleep/wake states and sleep stages as well as a Respiratory indices chart.

Definitions:

Sleep Time: Total time in hours, during which the patient is asleep.

PAT Respiratory Disturbance Index (pRDI): the estimated number of respiratory events divided by the valid sleep time. Provided in Respiratory Events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

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PAT Apnea Hypopnea Index (pAHI): the estimated number of Apneas and Hypopneas events divided by the valid sleep time. Provided in Apnea and Hypopnea events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

Oxygen Desaturation Index (ODI): the number of oxygen desaturation events (4% minimum desaturation) divided by the valid sleep time. Provided in Desaturation Events/Hour. The index is calculated during "All Night", REM and Non REM valid sleep time.

REM % of Sleep Time: REM sleep stages as percent of total sleep time.

Snore level in dBs: Because snoring can be a sign of sleep apnea, zzzPAT provides snore statistics. The threshold is determined according to DB. The amount of snoring is calculated as the percentage of sleep time over the specified DB threshold. The snoring volume level is graphically displayed (40 – 90 dB range).

Body Position: Five body position levels are graphically displayed (supine, right, left, prone and sit). Because the frequency of apneic events during sleep depends on patient position and sleep stage, zzzPAT provides information about the duration of sleep per each position – supine, prone, left, right, and sit. The corresponding percentage of time spent in each sleep position is displayed in a graph. Moreover, all recorded events such as respiratory disturbance index (RDI), apnea/hyperpnoea index (AHI), and desaturation index (ODI) are also provided in the report for each body position.

The Snore/Body Position data is displayed in a chart as shown here:

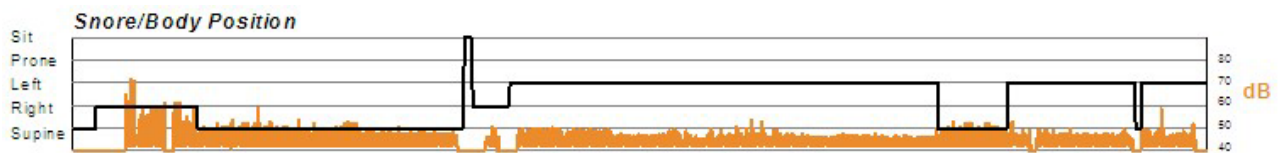



Figure 65 - Snoring and Body Position Statistics

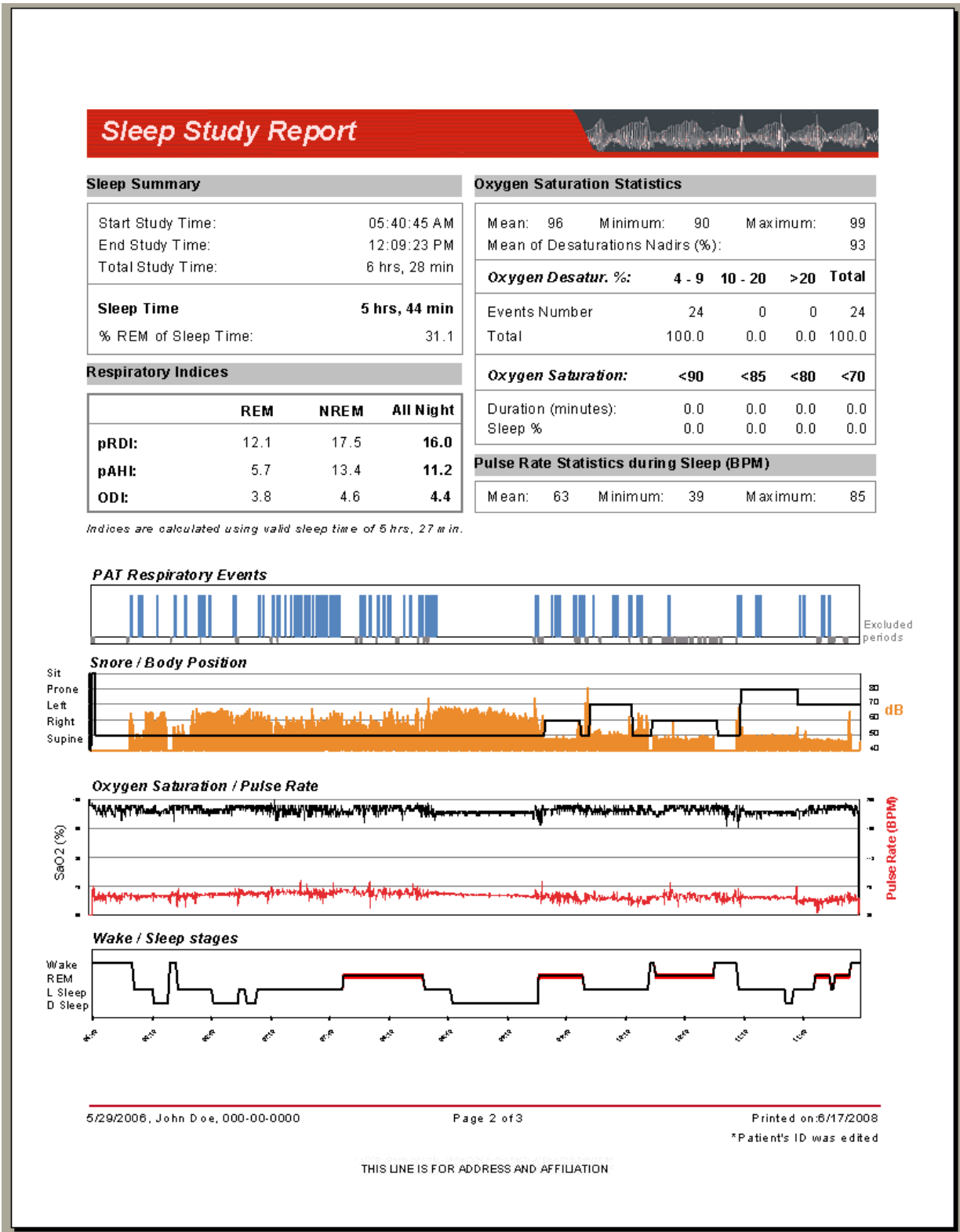
	<p style="text-align: center;">Note</p> <p>Several additional parameters such as Sleep Latency, REM Latency, Number of wakes and Sleep Efficiency are calculated but are only seen when using the "Export to csv" function (see Tools>Export/Delete)</p>
---	--

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THIS PLACE IS FOR THE PRACTICE LOGO		THIS LINE IS FOR ADDRESS AND AFFILIATION	
		THIS LINE IS FOR ADDRESS AND AFFILIATION	
Sleep Study Report			
Patient Information			
First Name:	John	Last Name:	Doe
Birth Date:	10/10/1953	Age:	52
Insurer:		BMI:	
Neck Circ.:		Epworth:	
Address:			
Sleep Study Information			
Study Date:	2/ 7/2005	S/H/A Version:	3.0.49.1 / 1.8 / 50
Referring Physician Information			
First Name:	John	Last Name:	Doe
Work Phone:	415- 482-9865	Mobile Phone:	
		E-mail:	
		Fax:	
Medical Information			
Medical History			
Asthma			
Chronic/Allergic rhinitis/sinusitis			
Medications			
Inhaled Beta-agonist			
Nasal decongestants			
Summary & Diagnosis			
Mild Sleep Apnea			
Physician Name:		Signature:	Date:
2/ 7/2005, SAMPLE STUDY1, SAMPLE_STUDY1			
Page 1 of 2			
Printed on:6/17/2008			
THIS LINE IS FOR ADDRESS AND AFFILIATION			

Figure 66 - First page of Sleep Report

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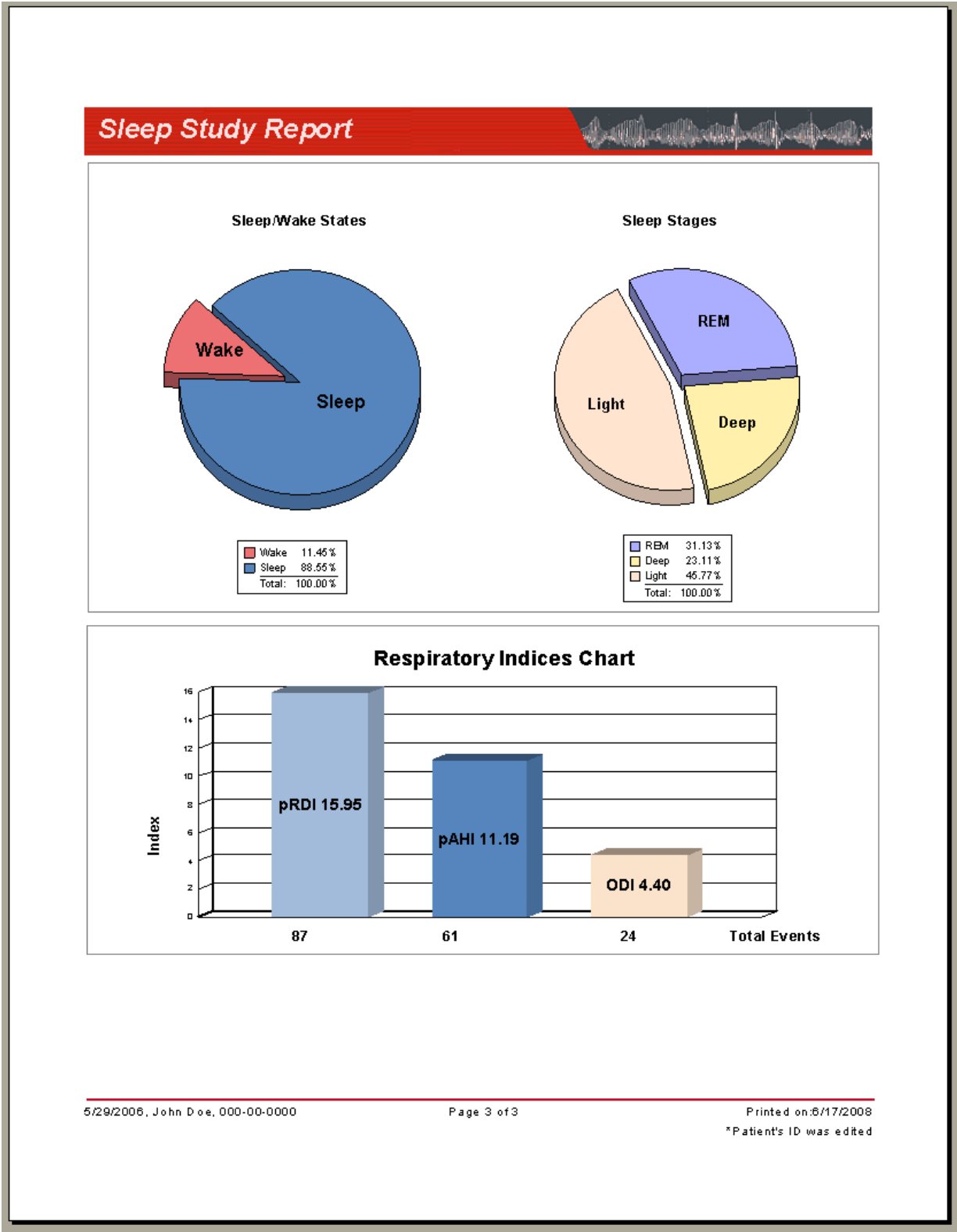


Figure 68 - Third page of Sleep Report (USA version)

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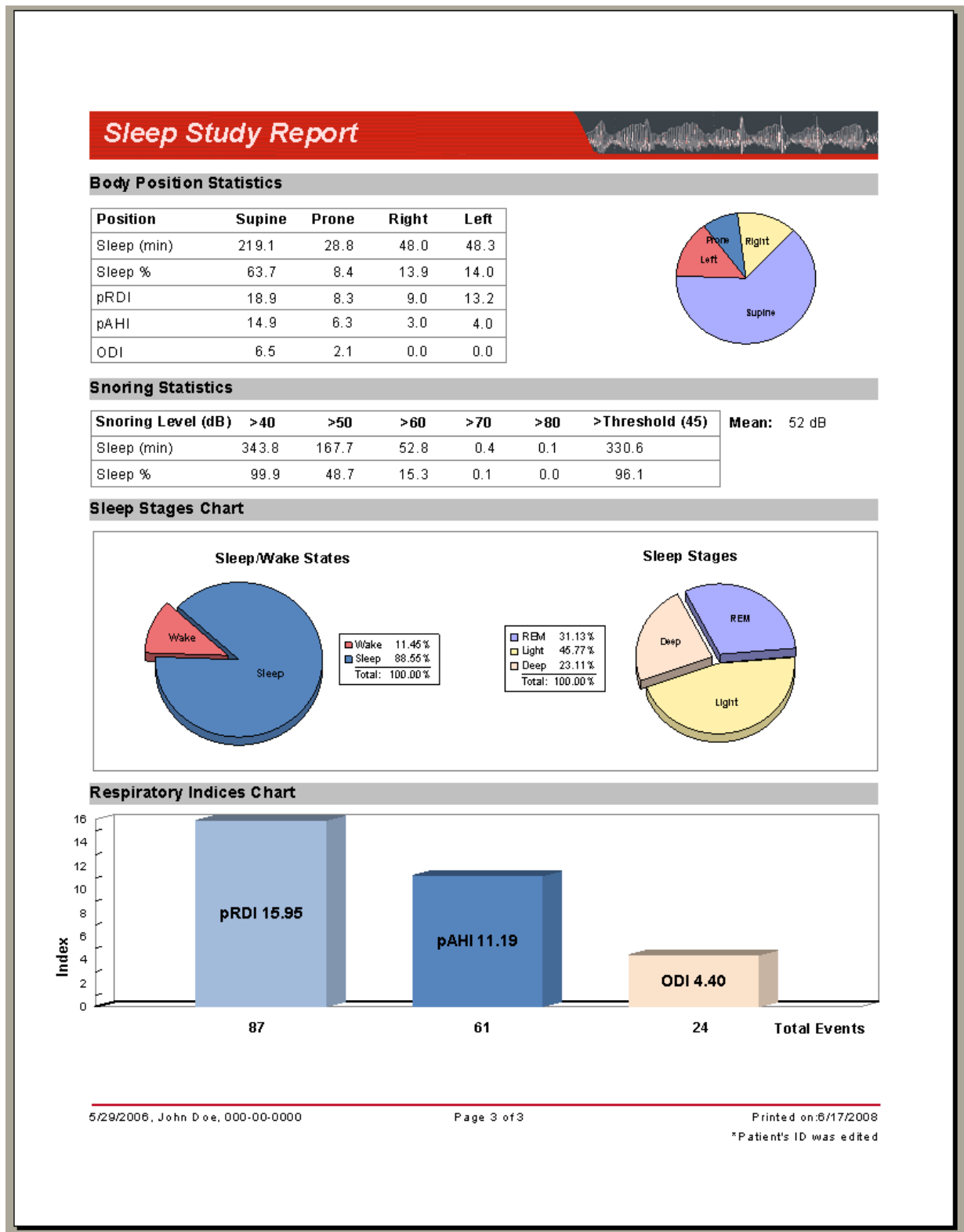


Figure 69 - Third page of Sleep Report (non-USA version)

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4.6.3 Report>Sleep Report for Selected Time Range

Generates a two-page report that provides a summary of the subject's sleep study in a **Selected Time Range** that is selected by the user.

The Selected Time Range report has the following title on the header of each page:



Figure 70 - Sleep Report for Selected Time Range Title


To generate a report for a selected time range:

- highlight the desired section of the waveform in the Signals Display Window, by clicking and dragging the mouse.
- click **Report>Sleep Report for Selected Time Range**.

The first page of the report includes Patient Information, the Sleep Study Information, Referring Physician, Medical history, Diagnosis and Recommendations.

The second page of the report presents the study results for the **Selected Time Range**, including Sleep Summary, PAT Respiratory Disturbance Index (pRDI), PAT Apnea Hypopnea Index (pAHI), Oxygen Saturation Statistics including the Oxygen Desaturation Index (ODI), mean, maximum and minimum oxygen saturation levels, Oxygen Saturation analysis, Pulse Rate statistics and REM Sleep analysis. It also includes graphical displays of Respiratory Events, Oxygen Saturation, Pulse Rate, Wake/Light Sleep/Deep Sleep and REM stages.

The third page of the report presents pie charts of sleep/wake states and sleep stages as well as a Respiratory indices chart.

	<p style="text-align: center;">Note</p> <p>In the Selected Time Range report, the Start and End Study Times are the margins of the Selected Range.</p>
---	---

4.6.4 Report>Event Report

This report provides statistics on different event types identified by the zzzPAT automatic analysis and by the User. A graphical representation provides a quick way of looking at the event distribution, and the summary section provides statistical information. When displayed on screen, the user can double-click on a particular event type (either on the chart or on the relevant row below the chart) to get a detailed list of all the events of this type (see Figure 71 - Event Report).

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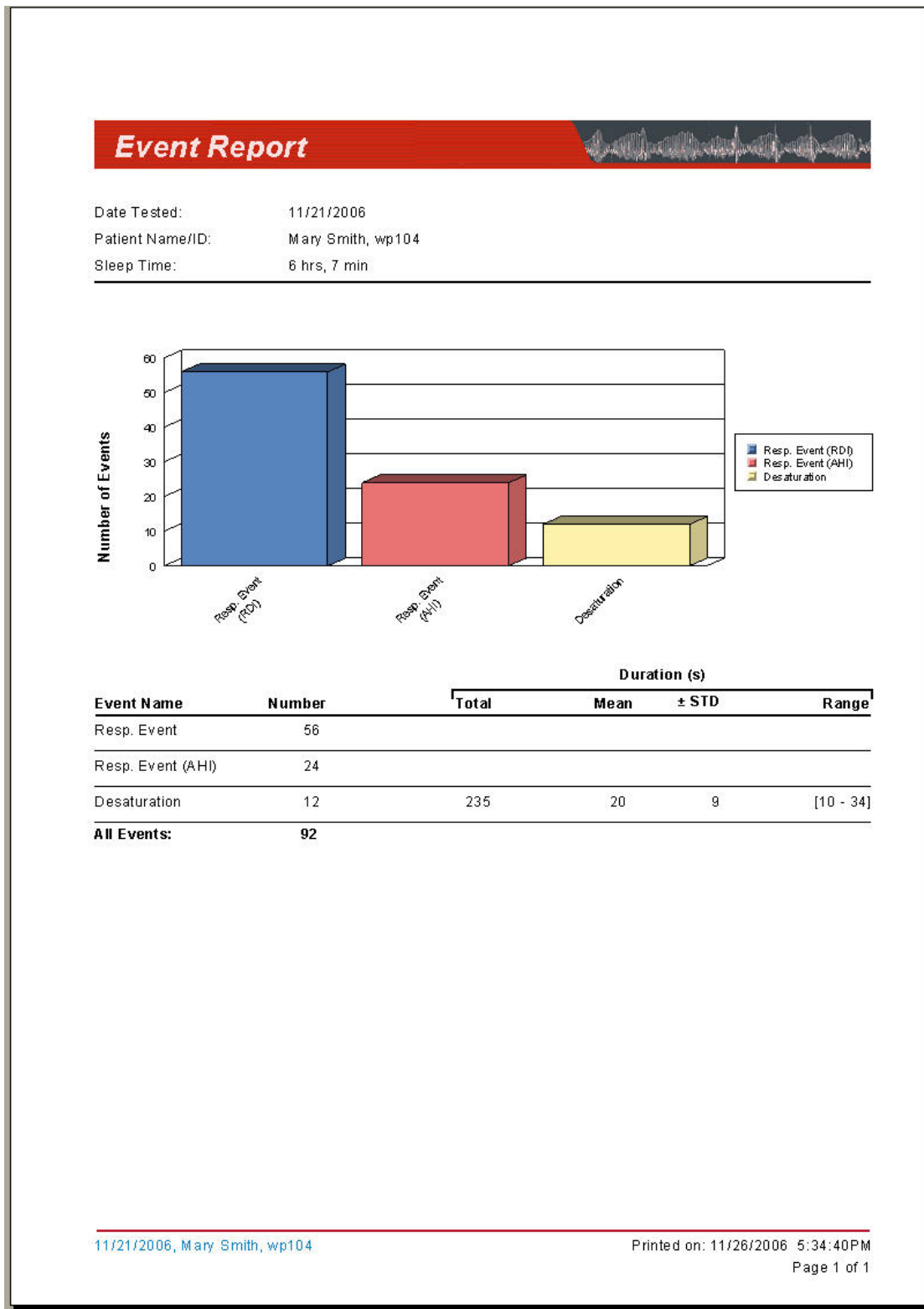



Figure 71 - Event Report


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	<u>Time Start</u>	<u>Time End</u>	<u>Time Duration (s)</u>	<u>Percent</u>	
Desaturation	1:00:46	1:21:22	10	4	
Desaturation	1:59:40	2:20:34	28	4	
Desaturation	2:00:17	2:20:53	10	4	
Desaturation	2:02:01	2:22:56	29	6	
Desaturation	2:03:17	2:23:57	14	4	
Desaturation	2:05:17	2:26:03	20	4	
Desaturation	2:13:41	2:34:19	12	4	
Desaturation	2:17:05	2:37:46	15	4	
Desaturation	5:58:06	6:18:51	19	4	
Desaturation	5:59:27	6:20:24	31	5	
Desaturation	6:02:44	6:23:44	34	5	
Desaturation	6:04:38	6:25:17	13	5	
Desaturation	12	235	20	9	[10 - 34]

Figure 72 - Detailed Event Report



Note


Click on the upper right icon  to close the details screen and return to the main report.

4.6.5 Report>Sleep Indices

This report provides a summary of study results, including pRDI, pAHI, ODI and Sleep Time.

Sleep Indices			
pRDI:	9.2	pAHI:	5.8
ODI:	3.4	Sleep Time:	8 hrs, 37 min

Figure 73 - Sleep Indices report



Note

Generation of the "Sleep Report" will close the "Sleep Indices" report.

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4.6.6 Report>Patient Follow-up Report

This report provides a way of comparing multiple studies for the same patient. A graphical representation of the pRDI, pAHI and ODI for the different studies provides a quick way of determining a trend through the studies.

In the European version of the report the Sleep % over 50 dB will be displayed as well.



Note

Unreviewed studies will not be presented in the Patient follow up report (see section 4.6.1).

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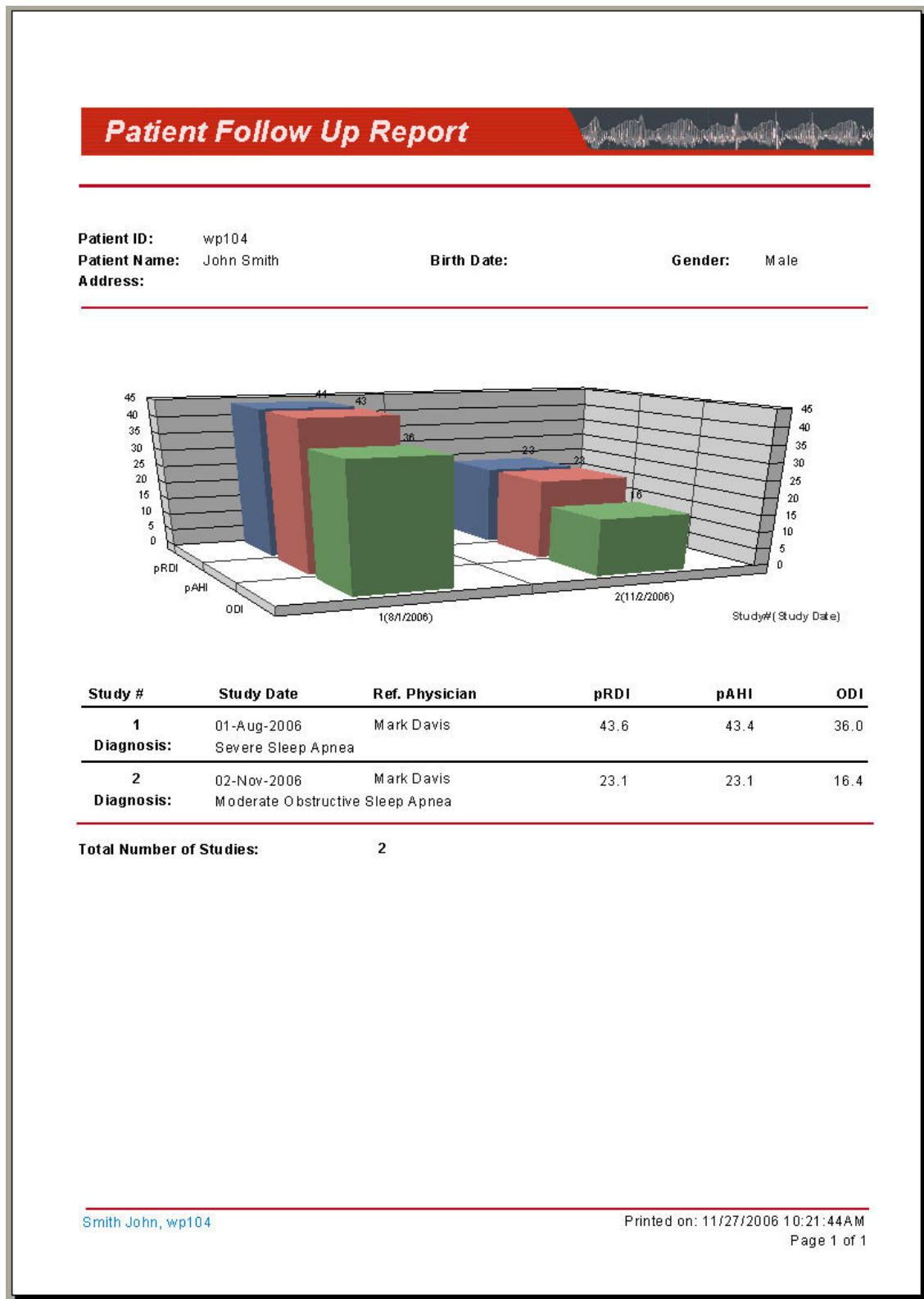


Figure 74 - Patient Follow Up Report (USA version)

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4.6.7 Report > Report for Patient

This report is designed in the form of a letter addressed to the patient that informs the patient about the sleep test results. It provides the following patient details:

- Total sleep time
- Apnea/Hypopnoea index (AHI)
- Respiratory disturbance index (RDI)
- Desaturation index (ODI)
- Rapid eye movement (REM)

It also compares these to the normal average indices.

To produce the report for the patient:

1. In the **Report** menu, choose **Report for Patient**.
2. Print the report by clicking on the Printer icon

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Sleep Study Report	
Name of Patient:	John Dow
Name of Referring Doctor:	
Date of Study:	2/3/2009
Dear John Dow,	
I would like to thank you for undertaking the Watch-PAT ambulatory sleep study. I would now like to review with you the results that you received.	
Your total study time (which is calculated from the time you turned the device on until you pulled it off) was 6 hrs, 11 min. But as we are testing for obstructive sleep apnea and are interested in the time that you were asleep, your total sleep time was 5 hrs, 9 min. On average, a person with normal sleep habits sleeps between 6 - 8 hours a night.	
Looking at your sleep statistics we can learn some vital information:	
Your apnea/hypopnea index (abbreviated as AHI) was found to be 18.6. This score is the average number of apnea and hypopnea events per hour of sleep during the night. Apnea event is an episode of fully occluded breathing of more than 10 seconds, and an hyponea event is an episode of partial occlusion. The normal range of the AHI score is 5 or lower.	
Your respiratory disturbance index (RDI) was found to be 23.1. This score is calculated in a very similar way as the AHI but an additional type of respiratory events named RERA are also counted. RERA is the abbreviation for Respiratory Effort Related Arousal and is essentially a very short arousal of a few seconds that follows partial occlusion of the airways. The normal range of the RDI score is also 5 or lower.	
Your oxygen desaturation index (ODI) was found to be 5.4. This score is the average number of times the oxygen in your blood dropped by 4% or more during an hour of sleep. As you can imagine, the more your oxygen drops the harder the heart must work. The normal range of the ODI is 5 or lower.	
Looking at your REM sleep stage (Rapid Eye Movement) we find that you were in this stage 20.9% of your sleep time. REM sleep is very important as during this stage your body is being replenished and nurtured. The normal range of the REM score is between 15 to 30% pending some other conditions. REM stage is also believed to be the time during which we dream.	
If I can be of any further assistance, please contact my front desk to make an appointment.	
Regards,	
Printed on: 10/27/2009	

Figure 75 - Letter to the Patient


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4.6.8 Printing

zzzPAT offers the user several printing options. This section describes various options of printing the displayed signals. zzzPAT reports printing is described in Section 0.

4.6.8.1 File>Print

The study signals recorded by the WP100 and the zzzPAT analysis can be printed by:

Either clicking on the print icon  on the toolbar or selecting **File>Print**.

User has a number of options for printing (Figure 76):

- Printing the entire study
- Printing the screen
- Printing specific sections defined by time range
- Printing specific channels

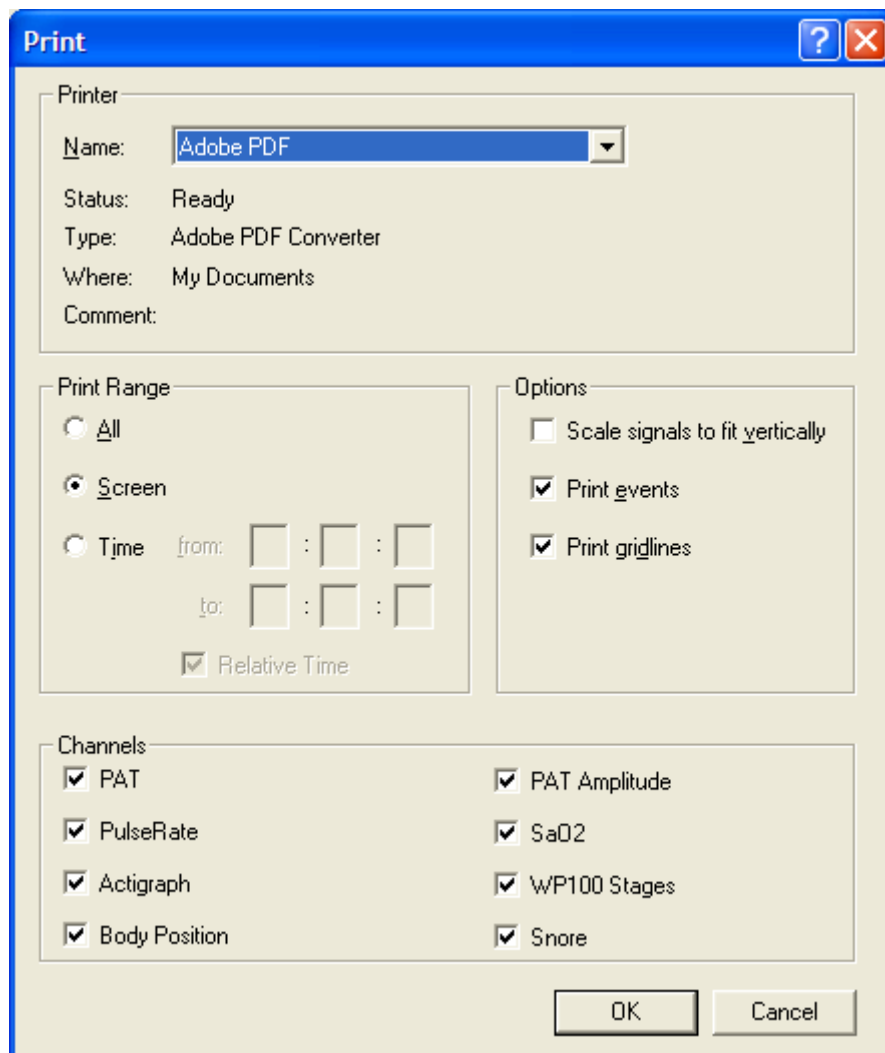


Figure 76 - Print dialog box

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5 Exporting Data

5.1 File>Export Data

Enables the user to export and save recorded signals data either in binary or EDF format.

5.2 File>Export Events - Creating *.txt File

Enables the user to export marked events into ACSII format. It creates an 'Event.txt' file that lists all events in a study by time of occurrence.

5.3 Tools>Export/Delete


See section 6.1.


5.4 Tools>Export General Settings

See section 6.5.

5.5 Transferring a Study to Itamar Medical

Used to save a study in a ZIP file, for transferring to Itamar Medical's support department. If zzzPAT has Internet access, this function allows the user to send the file directly, without saving first.

	<p>Note</p> <p>The signals data that is transferred to Itamar does not include any patient information.</p>
---	--

	<p>Note</p> <p>To use the zzzPAT ability to send files to Itamar, the zzzPAT station must have access to the Internet. If you not have access to internet use the alternative manual way to send signal data as describe in Appendix D: Manual Sleep data signal transfer.</p>
---	---

A study can be saved or transferred only if it is displayed in the 'Signals Display Window' or is stored in a Compact Flash card.

- Select a study:

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- by displaying it in the 'Signals Display Window'; or
- by inserting the Compact Flash card with the study into the Flash drive
- From zzzPAT click **Help>Prepare and Send Study to Itamar Medical...**

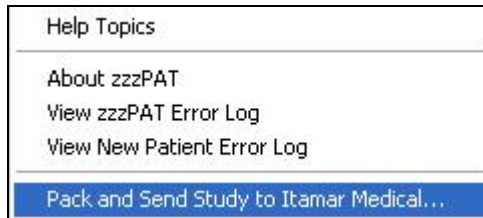


Figure 77 - Launching Transfer Files

The following Dialog Box appears:

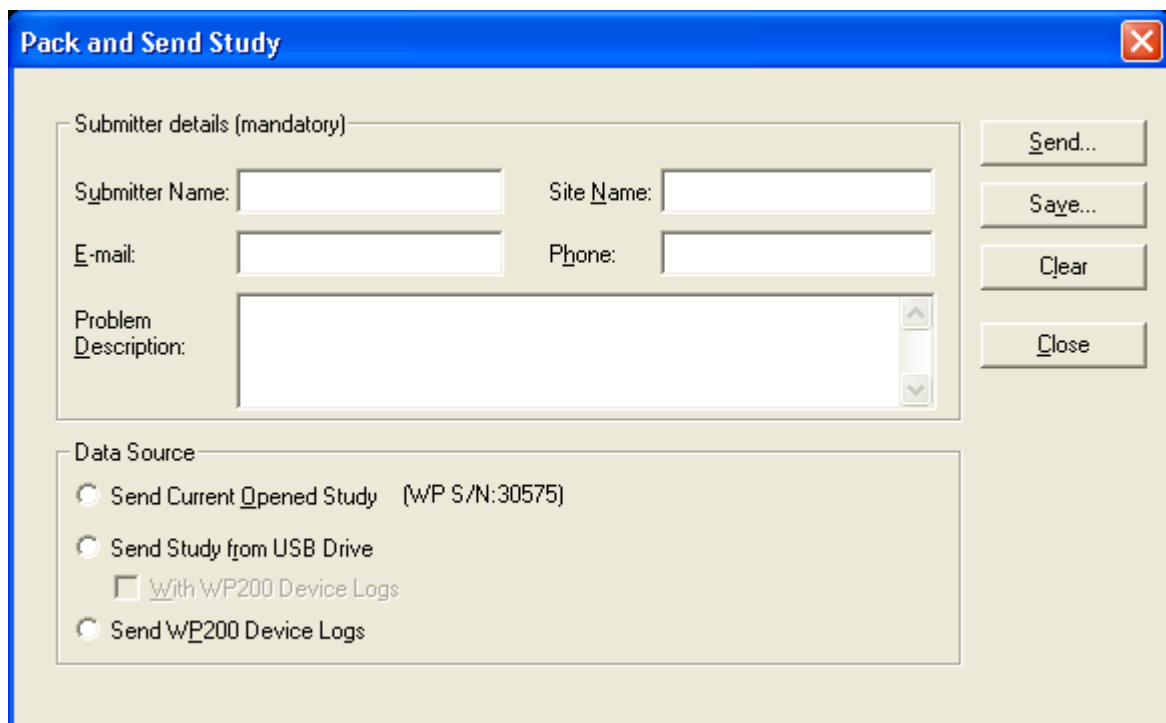


Figure 78 - Prepare and Send Study Dialog Box

- Select **Clear** to clear all fields. The last entered information is shown by default.
- Fill in the mandatory fields and check the radio button to indicate the desired option:
 - Check **Send Current Opened Study** if the case study is currently displayed on the Signal Window.
 - Check **Send Study From USB** if the case study is stored in the Compact Flash card (WP100) or in the WP200.
 - Check **Send WP200 Device Logs** in case the internal logs from the

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WP200 device needs to be sent to Itamar for troubleshooting.

- To save the study click **Save....** The following dialog box appears:

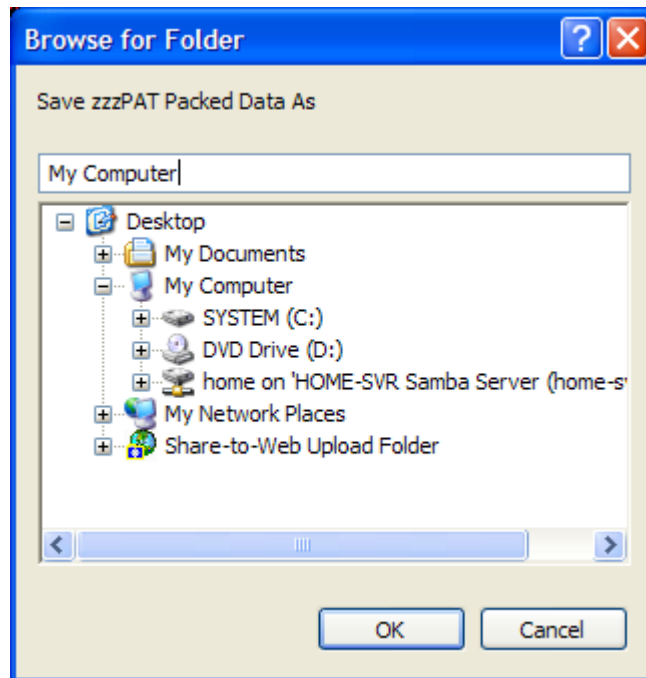


Figure 79 - Saving Case Study

- Select the destination for the saved file. The file will have the following name:
 - zzzPATPack_DT.zzpWhere
 - D is the current date
 - T is the current time

5.5.1 Sending a file to Itamar automatically

To transfer the study to Itamar Medical's support department:

- From zzzPAT click **Help>Prepare and Send Study to Itamar Medical...**
- Fill in the mandatory fields and check the radio button to indicate the desired option:
 - Check **Send Current Opened Study** if the case study is currently displayed on the Signal Window.
 - Check **Send Study From USB** if the case study is stored in the Compact Flash card.
- Click **Send....** The following screen appears:

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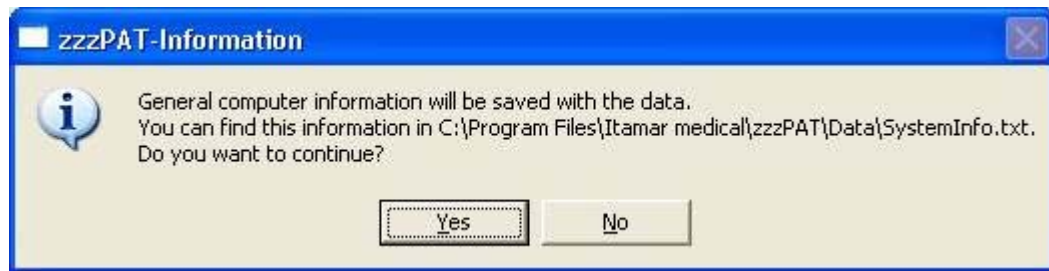



Figure 80 - Sending Study Confirmation

- Click **YES** to continue.

	<p style="text-align: center;">Note</p> <p>General information about the computer configuration will be included in the transferred file. This information does not contain any patient information.</p>
---	---

The progress of the file transfer will be reported on the following screen:

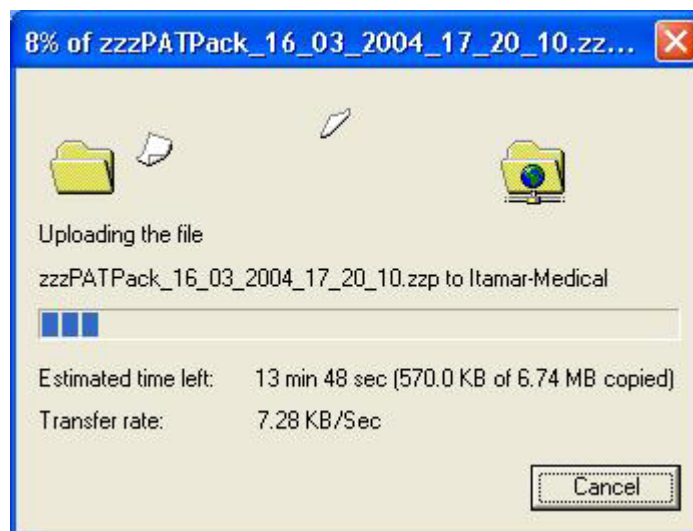


Figure 81 - Data Transfer Progress

Upon completion of the file transfer the following screen will appear:

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Figure 82 - Data Transfer Successfully Completed

- Click **OK** to continue.

5.5.2 Sending a file to Itamar manually

If the zzzPAT station does not have Internet access, or the automatic send failed to complete, the file can be sent manually using the following procedure:

- Save the file as described in Section 5.5
- Copy the saved file to a PC that has Internet access
- Launch Internet Explorer (or a similar Internet browsing application)
- Upload the file using the Itamar ftp server, see Appendix D: Manual Sleep data signal transfer

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6 Tools

6.1 Tools>Export/Delete

Allows the user to select the data of specific studies from the zzzPAT database and extract it to an archive database. This action enables freeing space on the PC hard disk, if needed, and archiving the data in other locations. Upon selection, the 'Export' dialog box will open:

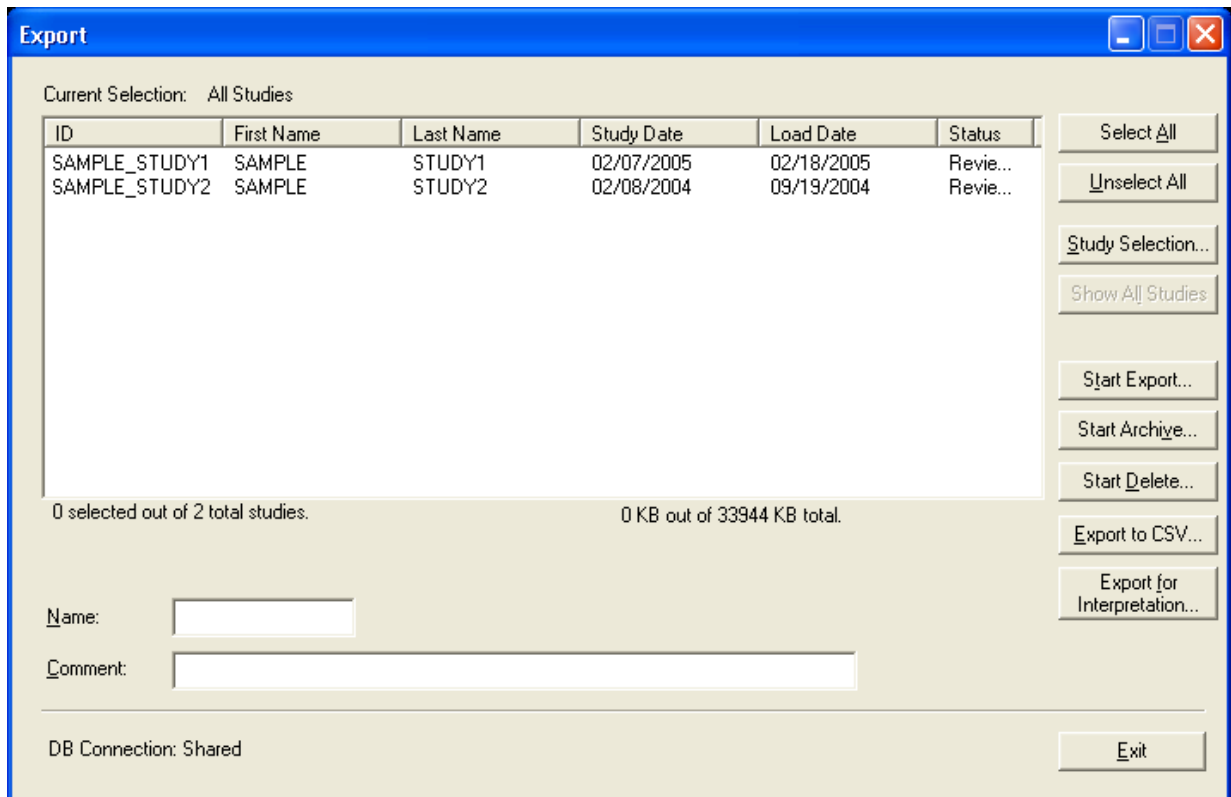



Figure 83 - Export Dialog box

This dialog box allows to export, archive or delete study data:

- **Export** function: Creates a file containing a copy of the selected study data as well as User's information for users associated with the exported files. Original files are not removed from the database.
- **Archive** function: Creates an archive file of the selected study data as well as User's information for users associated with the exported files, and removes the original data from the database.
- **Delete** function: Deletes the selected files from the database.

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- **Export to CSV** function: Creates a file named zzzPAT.csv, which contains in one line all the Patient, Study, Physician, and Analysis fields information. In case that a study has two different analysis, the data will be exported in two lines; one line for each entry.

	<p style="text-align: center;">Note</p> <p>Sleep Statistics values will be empty in CSV export for studies that had not a report issued.</p>
---	---

- The **Delete** function has two options, as seen in Figure 84.
- Delete files and save a temporary copy. The deleted files are saved to a temporary folder, overwriting the previously saved files from the last time the function was used and the option to save a temporary copy was chosen (this function always uses the directory ...\\Itamar Medical\\zzzPAT\\Data\\zzDELETE to save the deleted files).
- Delete studies permanently. The deleted files are deleted permanently.

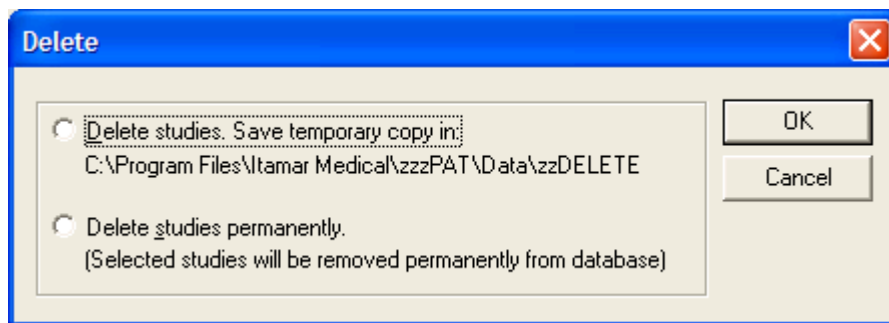


Figure 84 - Delete studies options Dialog box

- Temporarily saved deleted files can be restored by using the Import function of the Database Tools (see section 7.1.2).
- The temporarily saved file can be deleted from the hard disk (e.g. to free disk space) by following one of the below listed procedures:
- Delete one more study and select “Delete studies. Save temporary copy in:”. By doing so the previously saved deleted studies will be replaced by the single study deleted now, thus reducing the size of the saved files to one study only.
- Using Windows Explorer navigate to the folder that contains the saved deleted files (\\Program Files\\Itamar Medical\\zzzPAT\\Data\\zzDELETE) and delete its content in its entirety.

To commence Archive Export or Export to CSV operations proceed with the following:

- Name the archive (optional) in the ‘Name’ editing box (Name can consist of up to 8 characters).
- Add comments, if desired, in the ‘comments’ editing box.
- The exported/archived files will be saved in a folder named in accordance with the following convention:

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- Exported files: 'zzExport_name_dd_mm_yy_hh_mm' with "name" being the optional data entered by the user
- Archived files: 'zzARCHIVE_name_dd_mm_yy_hh_mm' with "name" being the optional data entered by the user
- Export to CSV files: 'zzzCSVExport_name_dd_mm_yy_hh_mm' with "name" being the optional data entered by the user
- You can apply a filter to the files listed in the main field, by clicking **Study Selection....** The following dialog box will open:

Figure 85 - Study Selection Dialog box

- To select studies by a specific criterion, check the box to the left of the desired criterion. In addition user can select whether to export studies by status: Unreviewed, Reviewed and Reported and by user predefined **Custom Fields** (see section 3.4.4). It is possible to select several criteria by which to export a single group of studies.

	<p style="text-align: center;">Note</p> <p>The Custom Fields section will appear in the 'Select Studies By' dialog box, only if the user predefined these fields. See section 3.4.4 for details.</p>
--	--


- Select the studies you wish to export/archive/delete from the main field in the Export dialog box. You can click **Select All** to select all files, or you can select individual files by shift or control clicking on them.
- Once ready, click:
- **Start Export** to export the selected studies, or,
- **Start Archive** to archive the selected studies, or,

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- **Start Delete...** to delete the selected studies, or,
- **Export to CSV** to export the selected studies to CSV format.
- Click **Exit** to close the Export dialog box.
- **Export for Interpretation** function: Prepares and copies the raw data files as one zipped file for later ftp upload to a secure server for interpretation services.

6.2 Tools>Import

Use to import previously archived studies that were removed from the zzzPAT database, back into the database. Upon selection the 'Import' dialog box will open.

	<p style="text-align: center;">Note</p> <p>Together with the imported studies zzzPAT imports user information of users associated with the imported files if such users are not defined in zzzPAT. These users are imported with Basic User Permissions only (see Section 2.9.2).</p>
---	---

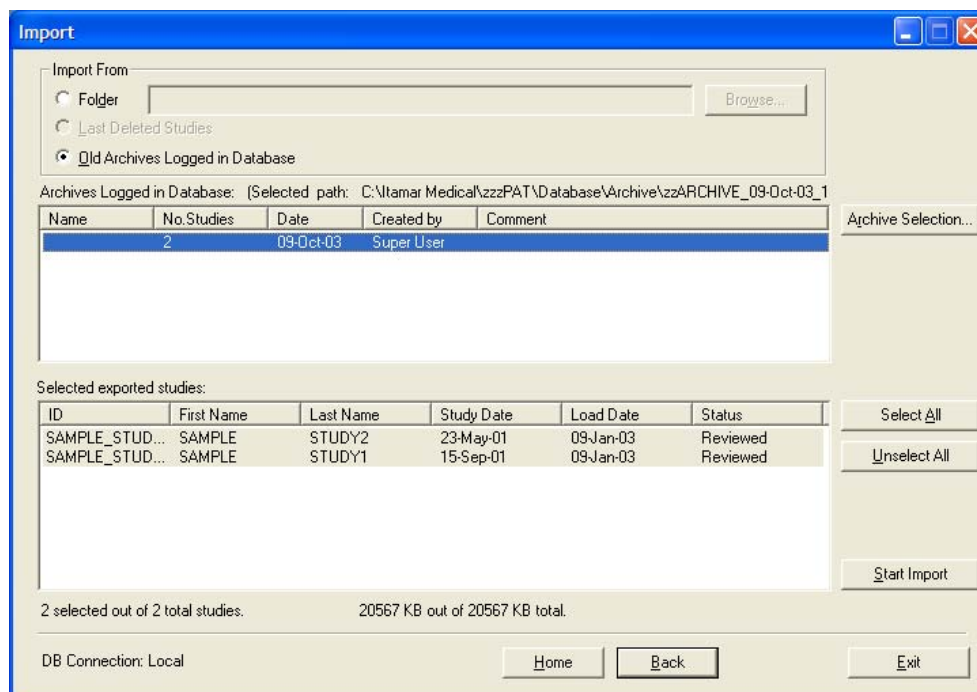


Figure 86 - Import Dialog Box

It is possible to locate the archived studies you wish to import by using the **Browse** option or by selecting them from a list of logged archives in the database. If previously deleted files were deleted using the "Save a temporary copy" option, selecting the Last Deleted Studies option will allow retrieval of these studies.


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Locating an Archive by browsing:

- Select the 'Folder' radio button in the 'Import' dialog box. The **Browse** button will become enabled.
- Click on the **Browse** button and select the file you wish to import.

Locating an Archive from a list of logged Archives in the database:

By default all archives will be displayed in the 'Old Archives Logged in Database' list. The user can filter the archives displayed in this list by certain criteria.

	<p style="text-align: center;">Note</p> <p>If the database was overwritten while upgrading zzzPAT or the database was erased due to restoring a back up database into it, no archives will displayed in the "Old Archives Logged in Database" Field.</p>
---	---

To filter the archives that will be displayed in the 'Old Archives Logged in Database' field:

- Select the "Old Archives Logged in Database" radio button.
- Click on the **Archive Selection** button. The following dialog box will open:

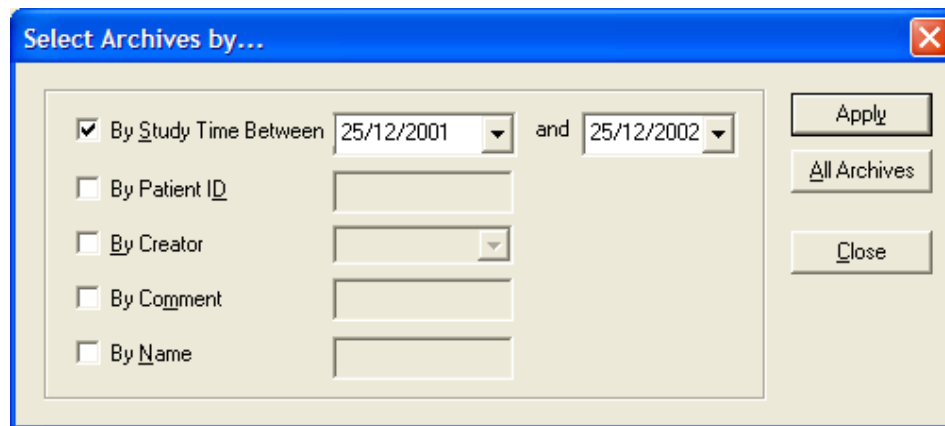



Figure 87 - Select Archive Dialog box

- Check the criteria by which you want to select the Archive.
- Insert the appropriate parameters for selection.
- Click **Apply**.
- Click **Close** to return to the 'Import' dialog box.
- You can restore the default display of all archives by clicking the **All Archives** button.
- Select the Archive you wish to import.

Once an Archive has been selected, all its studies will be displayed in the 'Selected exported studies' fields of the 'Import' dialog box.

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- You can select individual studies you wish to retrieve by clicking on them with the mouse while holding down the **Ctrl** key on the keyboard, or you can import them all by clicking on the **Select All** button.
- Click **Start Import** to begin the process.

	<p style="text-align: center;">Note</p> <p>You cannot import a study that is already available in the database</p>
---	---

6.3 Tools>Backup

Enables the user to copy the entire database to another location for back up. Upon selection the 'Backup' dialog box will open.

- Select the path for a backup directory by clicking on the **Browse** button, or by accepting the system default setting.
- Click **Start Backup** to begin the process.

Automatic Backup

A backup of the database for every day of the week will be automatically performed behind the scenes. Backing this way will minimize loss of data in case of database corruption. The backup of the database will be saved as zzPATday1.bak for Sunday, zzPATday2.bak for Monday, etc. The zzPATday1.bak will be overwritten next Sunday. The files will be saved under backup folder (C:\itamar medical\zzzpat\backup).

6.4 Tools>Restore

Use this application for restoring a backed-up database by overwriting the current database. Use this application to recover a database following a major database failure. Upon selection the 'Restore' dialog box will open.

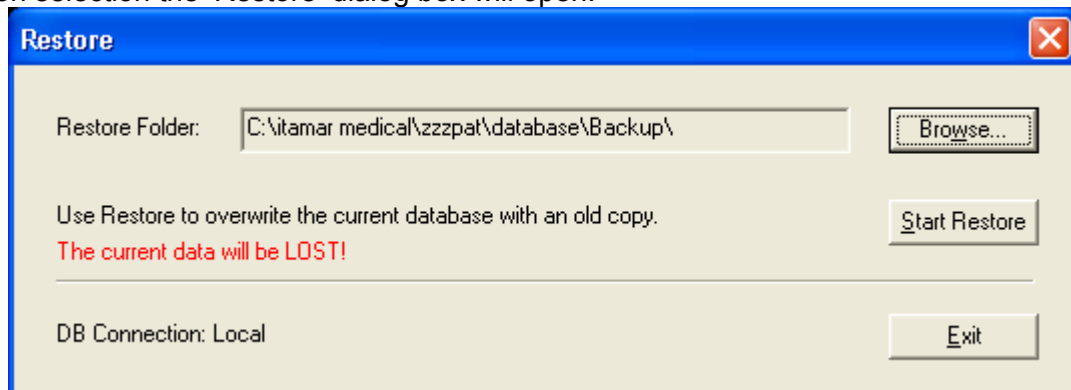



Figure 88 - Restore Dialog box

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	<p style="text-align: center;">Warning</p> <p>Restoring a backed-up database overwrites the current database replacing all the data it contained!!!</p>
---	--

6.5 Tools>Export General Settings

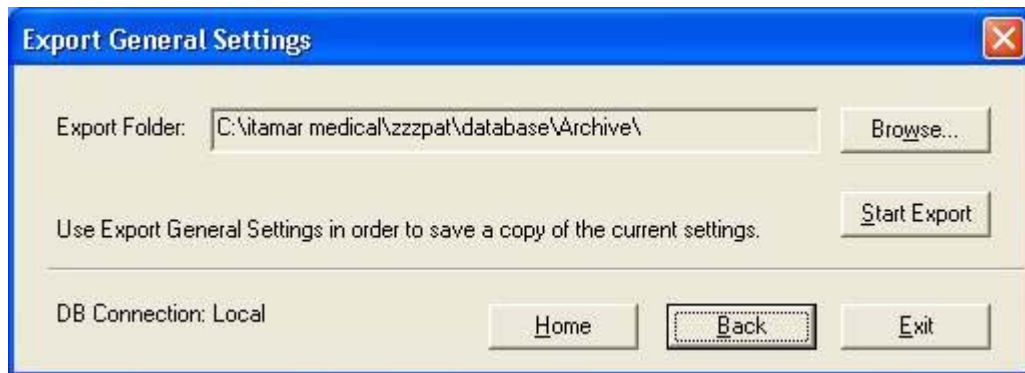


Figure 89 - Export General Settings Dialog Box

- Type the directory path or click '**Browse**' button to select the directory, where the General Setting configuration file will be saved.
- Click 'Start Export'.

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6.6 Tools>Import General Settings

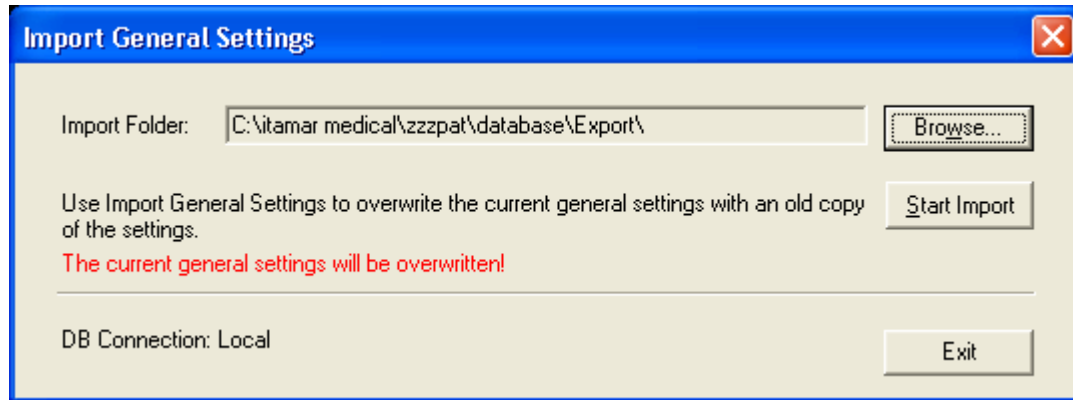


Figure 90 - Import General Settings Dialog Box

Click '**Browse**' to select the directory of the General Setting configuration file.

Click '**Start Import**' to continue.

6.7 Tools>User Administration

Please refer to Section 2.9.

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7 Database Wizard

The zzzPAT Database Wizard contains three utilities:

Database Tools - Allows an authorized administrator to update and maintain the zzzPAT database.

User Administration - Allows an authorized administrator to add users to zzzPAT application and define the permissions attributed to them. (See chapter 2.9).

Configuration Tools - Allows an authorized administrator to Export and Import the General Settings.

- Select Start>Programs>zzzPAT>Database Wizard.

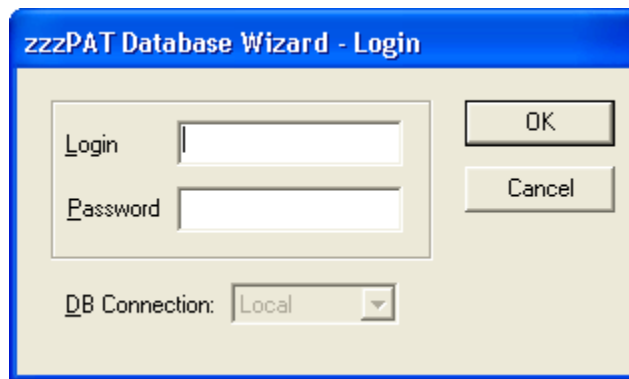


Figure 91 - Database Wizard Login

- Enter Login and Password, and select the desired database Connection.
- The Database Wizard will open:

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Figure 92 - Database Wizard

7.1 Database Tools

Click on the 'Database Tools' icon . The following dialog box will appear:

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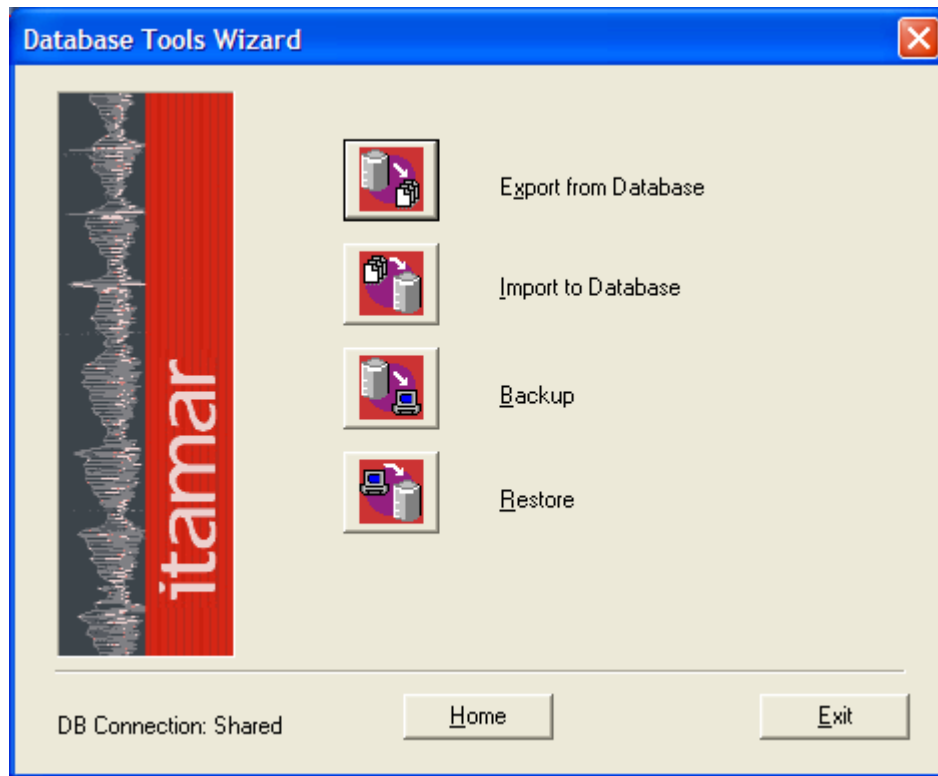




Figure 93 - Database Tools Wizard dialog box


7.1.1 Export From Database:

- Click the 'Export From Database' Icon  in the 'Database Tool Wizard' window.
- Refer to Section 6.1 for a detailed explanation of the exporting procedure.

7.1.2 Import to Database

- Click on the 'Import to Database' icon  in the 'Database Tools Wizard' window.
- Refer to Section 6.2 for a detailed explanation of the importing procedure.

7.1.3 Backup

- Click on the 'Backup' icon  in the 'Database Wizard Tools' window.
- Refer to Section 6.3 for a detailed explanation of the backup procedure.

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7.1.4 Restore

- Click on the 'Restore' icon  in the 'Database Wizard Tools' window.
- Refer to Section 6.4 for an explanation of the restoring procedure.

7.2 User Administration

Please refer to Section 2.9.

7.3 Configuration Tools

Used to copy General Settings from one zzzPAT station to another (see Figure 92).

Click the configuration tools icon . The following screen appears:

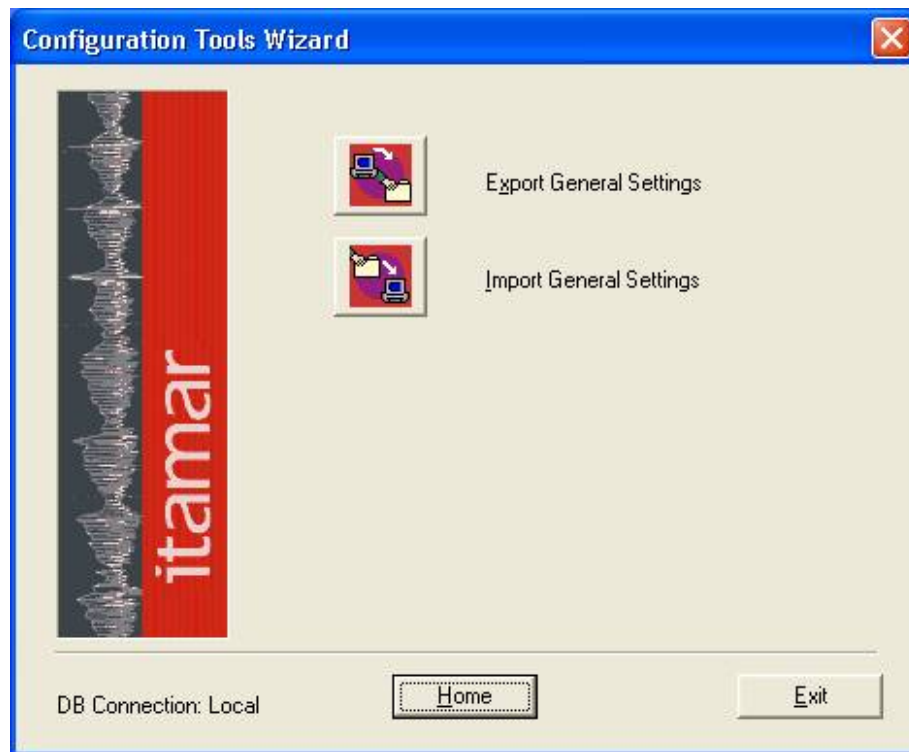



Figure 94 - Configuration Tool Wizard

- Click the 'Export General Settings' icon  to save the current General Settings configuration.


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- Click the 'Import General Settings' icon  to apply a saved General Settings configuration.

7.3.1 Export General Settings

- Click the 'Export General Settings' icon .
- Refer to Section 6.5 for a detailed explanation of the general settings exporting procedure.

7.3.2 Import General Settings

- Click the 'Import General Settings' icon .
- Refer to Section 6.6 for a detailed explanation of the general settings importing procedure.

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8 Troubleshooting

Installation		
Trouble	Possible Cause	Solution
zzzPAT installer fails to run.	Auto run function in Windows is not activated.	Open My Computer>zzzPAT CD and double click 'Setup.exe'.
	Windows version not compatible with zzzPAT.	Must have Windows 2000 or Windows XP for zzzPAT installer to run.
	Hardware configuration below minimum required.	Must have at least 128 MB RAM, and a Pentium processor for zzzPAT installer to run.
zzzPAT fails to recognize flash drive.	Compact Flash drive not installed	Install Compact Flash drive, when done, insert a CF card, run zzzPAT and select Setup>Set USB Drive (see section Setup>Set USB Drive)
	Compact Flash drive needs to be re-defined.	Insert a CF card, run zzzPAT and select Setup>Set USB Drive (see section Setup>Set USB Drive)
Under Windows XP, user cannot load study or operate 'Database Wizard' utilities, despite having proper zzzPAT user permissions.	User does not have writing permission to the drives these applications are located on.	Check user's writing permissions per section, and redefine as necessary.

Table 2 - Troubleshooting, Installation

zzzPAT		
Trouble	Possible Cause	Solution
Analyze>Reload Study and Analyze option in the zzzPAT window is disabled	User does not have permission to operate this utility.	zzzPAT Administrator can modify user's Extended Permissions. (See section 2.9)
	Insufficient free space on hard disk	Free enough disk space to exceed the minimum requirement of 100MB and try again
Cannot Load Study (function is disabled)	There is less than 200MB of free hard disk space	Free enough disk space to exceed the minimum requirement of 200MB and try again
zzzPAT will not start, or behaves unpredictably	Some zzzPAT files may be damaged/overwritten	Uninstall and reinstall zzzPAT.

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The open file does not show REM	File was saved with an older version of zzzPAT that did not have REM capabilities	Run the analysis by selecting Analyze>Reload Study and Analyze
Events Report does not show defined header, footer and logo	The Report Appearance setting tab applies only to the Sleep Report	NA
Cannot generate Sleep Report - Sleep Report button is grayed out	Less than 100MB of free disk space	Free enough disk space to exceed the minimum requirement of 100MB and try again
	No study is loaded or study is non valid	Open the desired study. If the study is open, it may have invalid data and therefore is not usable
User cannot log on to zzzPAT	On Windows XP and Vista zzzPAT will not open if another session is open under a different user	Ensure no other user left an open zzzPAT session on the PC. If you cannot verify, restart PC
	User is not defined in zzzPAT	Define user by zzzPAT administrator
Send report by email fails	zzzPAT does not support Netscape as the email application	Define Microsoft Outlook (or Outlook Express) as the default mail client
Changes to Events Names do not show up on screen	Events names are saved with the saved analysis. Changes will become visible only after running analysis again	Run the analysis by selecting Analyze>Reload Study and Analyze
Errors while printing	Non-compatible printer driver	A postscript printer driver provides the most reliable operation with the zzzPAT. Install a suitable postscript driver for the printer in use and try again
After clicking New Study in zzzPAT the dialog box disappears and zzzPAT is frozen	Inadvertent double clicking the New Patient button may cause the dialog box to be hidden in the background	Press Alt-Tab to bring the dialog box back to the front
"Enable multi-night option" does not show in New Study dialog	The WP200 has S/W version lower than 2.2182	Upgrade the WP200 S/W to the newest S/W (call Itamar Help Desk for the upgrade)
"Enable tamper-proof testing option" does not show in New Study dialog	The WP200 has S/W version lower than 2.2182	Upgrade the WP200 S/W to the newest S/W (call Itamar Help Desk for the upgrade)

Table 3 - Troubleshooting, zzzPAT

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Shared Access Mode zzzPAT		
Trouble	Possible Cause	Solution
User cannot log on to zzzPAT	In Shared Access mode user may be defined in the shared database and not in the local one, or vice-versa	Define user in the second database, or, Exit zzzPAT and log on to the other zzzPAT database (either local or shared)
Cannot find saved file	File saved to the other database (either the local or shared database)	<ul style="list-style-type: none"> • Verify to which database zzzPAT is connected (the database connection appears in the zzzPAT status bar) • Exit zzzPAT • Start zzzPAT and select the other database to connect to • Select File>Open and search for the desired file
Shared database is not available	Network is disconnected	<ul style="list-style-type: none"> • Make sure the zzzPAT station is properly connected to the network, and that network services are available to it. Consult your system administrator if necessary
Cannot open selected study	Study is in use by another zzzPAT user	<ul style="list-style-type: none"> • Wait until the other user closes the study and try again

Table 4 - Troubleshooting, Shared Access Mode zzzPAT

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Utilities		
Trouble	Possible Cause	Solution
Preparing Compact Flash card for new study failed	Compact Flash card was removed from the Compact Flash reader before 'New Study' details were saved to it	Do not remove Compact Flash card from the Compact Flash reader before Figure 41 dialog box appears
WP100 only: New Study or zzzPAT do not recognize the Compact Flash card	Critical files were erased from the Compact Flash card	Using Windows Explorer, copy files patient.dat and sleep.dat from Program Files\Itamar Medical\zzzPAT\Misc to the Compact Flash card, and try again
	Compact Flash card was formatted to an unsupported format	Reformatted Compact Flash cards cannot be used with the Watch-PAT system and have to be replaced
WP200 only: New Study or zzzPAT do not recognize the WP200	Critical files were erased from the internal sd card or the volume name has been erased	Format drive with volume name "WP200" and then copy files patient.dat, sleep.dat and wp200-comm.dat from Program Files\Itamar Medical\zzzPAT\Misc to the WP200 drive
Database Tools button in the 'Database Wizard' window or Tools in zzzPAT is disabled	User does not have permission to operate this utility	zzzPAT Administrator can modify user's Extended Permissions (See section 2.9)
User Administration button in the 'Database Wizard' window or Tools>User Administration is disabled	User does not have permission to operate this utility	zzzPAT Administrator can modify user's Extended Permissions (See section 2.9)
Database Tools does not open	zzzPAT or New Study is running	Close zzzPAT or New Study and open Database tools
Super User forgot his password	-	Contact Itamar Medical Representative

Table 5 - Troubleshooting, Utilities

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You may only transfer or assign the rights and obligations hereunder together with the Licensed Software and/or the Licensed Product or Third Party Product as a whole, without retaining any rights or, subject to Sections 2 and 3 above, any obligations arising after the date of such transfer or assignment, or retaining any installed or uninstalled copy of the Licensed Software, the Licensed Product or the Third Party Product. Any attempt by you to rent, lease, sublicense, assign or transfer any of the rights, duties or obligations hereunder in any other way is forbidden and shall be null and void.

8. SEVERABILITY

Should any term or provision of this License Agreement be declared void or unenforceable by any court of competent jurisdiction in any country or countries, such declaration shall have no effect on the remainder of this License Agreement in such country or countries, or on this License Agreement in other countries.

9. NO WAIVER

The failure of either party to enforce any rights granted to it hereunder or to take action against the other party in the event of any breach hereunder shall not be deemed a waiver by that party as to subsequent enforcement actions in the event of future breaches.

10. GOVERNING LAW AND JURISDICTION

This License Agreement is governed by the laws of the State of New York, excluding its conflict of laws principles. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to any of the transactions contemplated by this License Agreement.

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Note: Should you have any questions concerning this License Agreement, or if you desire to contact Itamar for any reason, please write to: Itamar Medical Ltd., 9 Halamish St., P.O.Box 3579, Caesarea, 38900, Israel, Facsimile: +972-4-627 5598, or visit Itamar's web site at www.itamar-medical.com.

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Appendix B: TECHNICAL SUPPLEMENT

The zzzPAT uses a set of algorithms and provides automatically the following indices and events:

- Sleep-wake events using the Automatic Sleep-Wake Algorithm (ASWA).
- Respiratory events index which includes Apnea Hypopnea and RERA: pRDI (PAT Respiratory Disorders Index).
- Apnea and Hypopnea Index: pAHI (PAT Apnea and Hypopnea Index).
- Oxygen Desaturation Index ODI.
- REM (REM) events using the Automatic REM Detection Algorithm (ARDA).
- Deep and Light Sleep (s1,s2 is light) and s3-s4 is Deep sleep.

Sleep-Wake

The sleep-wake output, obtained in 30 seconds epochs, is used by the other three algorithms to apply calculations in sleep sections only, while skipping over the wake sections.

pRDI and pAHI

pRDI expresses the number of PAT respiratory events per hour of sleep, the index includes the following events: Apnea and Hypopnea and RERA (respiratory effort related arousal).

pAHI expresses the number of Apnea and Hypopnea per hour of sleep.

These events are derived from the following physiological parameters measured by the WP100:

- PAT signal amplitude - acquired by a pneumo-optical finger probe that measures the vasomotor changes of the arterial blood vessels in the finger. This reflects changes in sympathetic activity.
- Pulse rate - derived from the above PAT signal.
- Blood Oxygen saturation level - determined by an embedded pulse Oximeter.

The first two parameters are associated with sympathetic activity related to respiratory episodes. The third parameter, oxygen saturation level decreases (desaturation) during a respiratory event. Actigraphy movement is often associated with respiratory episodes. These four physiological parameters are incorporated into two different decision- making processes that define, for each epoch identified as a sleep epoch and breathing disorders. These processes are described in the attached flow diagram.

ODI

This index expresses the number of Oxygen desaturation events during an hour of sleep. Desaturation event is determined when there is a reduction of 4% of the oxygen saturation baseline. The index includes the events that occurred during sleep time, and it does not includes events occurred during wake periods.

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REM

REM events are determined for sleep epochs only, based on information extracted from local windows applied to the amplitude and pulse-rate time-series of the PAT signal. For each epoch four parameters are extracted:

- Mean PAT amplitude time-series
- Scaling-exponent of the amplitude time-series using Detrended Fluctuation Analysis (DFA).
- Ratio of peak low-frequency-band to high-frequency-band in the PAT amplitude time-series spectrum.
- Ratio of peak low-frequency-band to high-frequency-band in the PAT pulse-rate time-series spectrum.

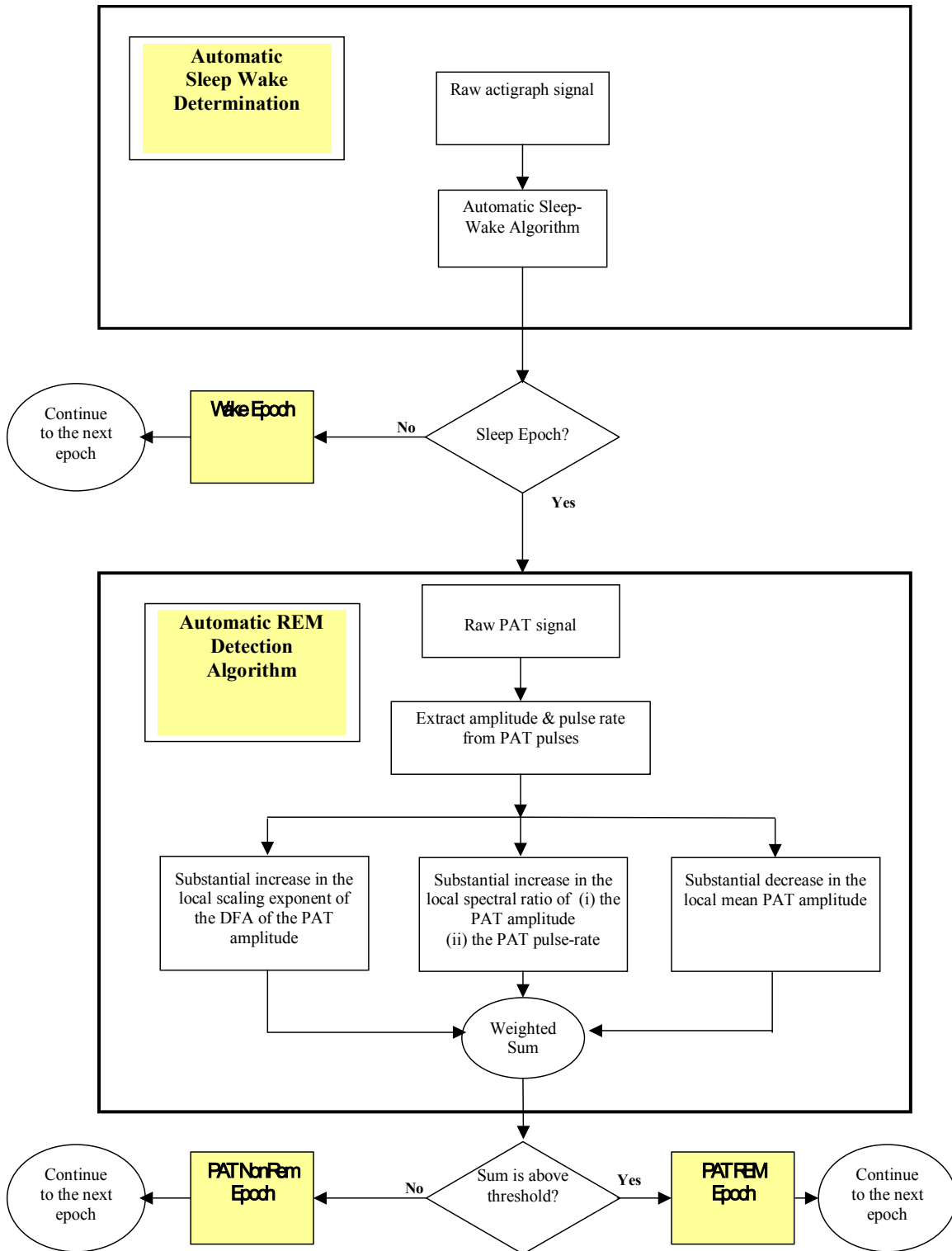
These algorithms were optimized in clinical studies using simultaneous study of Watch-PAT with automated zzzPAT analysis, and in-lab standard polysomnography (PSG) recordings, which were scored manually according to the American Academy of Sleep Medicine (AASM) criteria. This set of sleep studies was defined, according to correct practice, as a training set. Once finalized, a separate set of studies was used to validate the algorithms.

DEEP and Light sleep

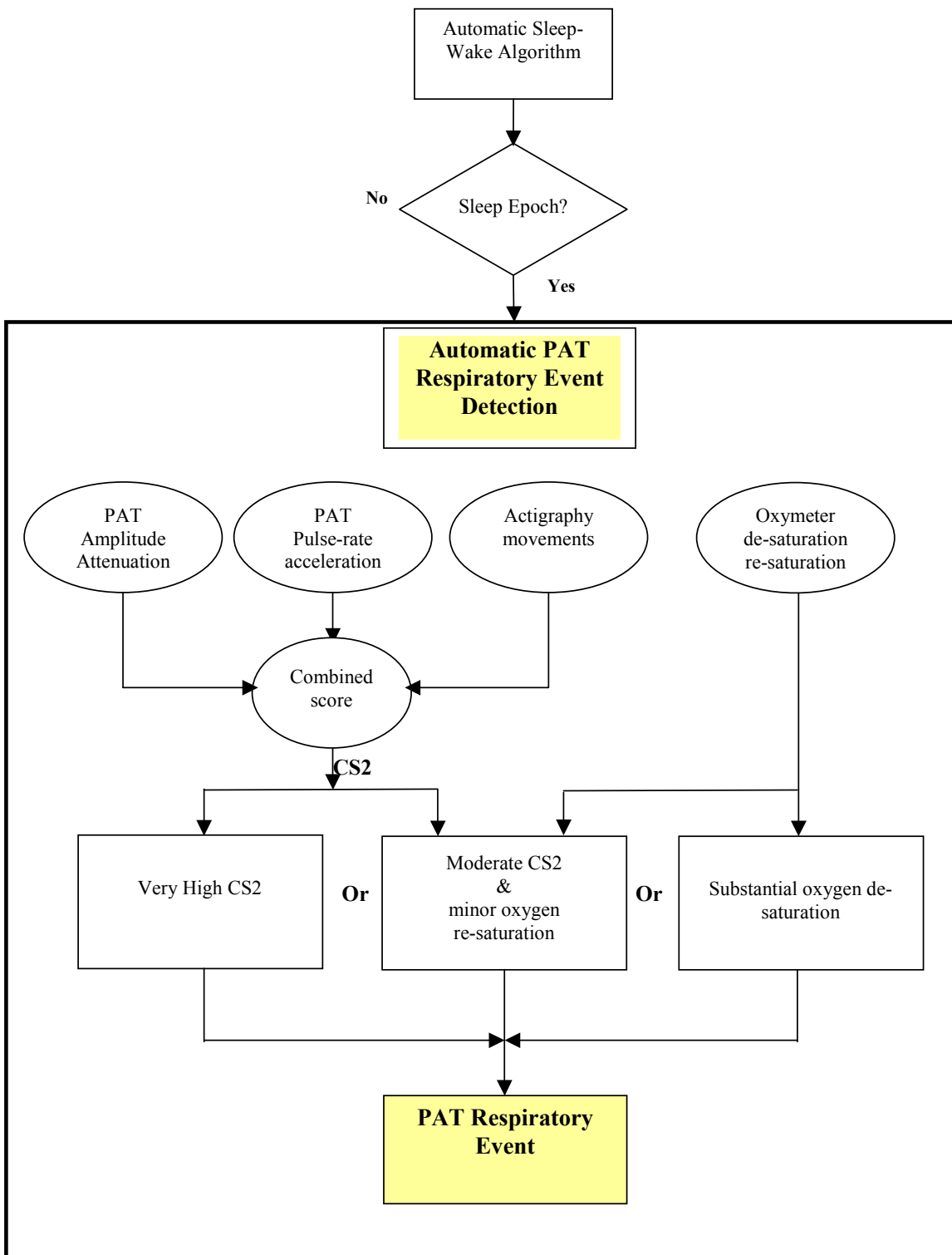
Epoch of Deep and light sleep are identified using the very same transformation of PAT amplitude and Pulse rate than for REM. This Provides the full PAT Hypnogram.

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ZZZPAT analysis flow diagram



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Appendix C: Keyboard Shortcuts

General:

In all dialogs or menus:

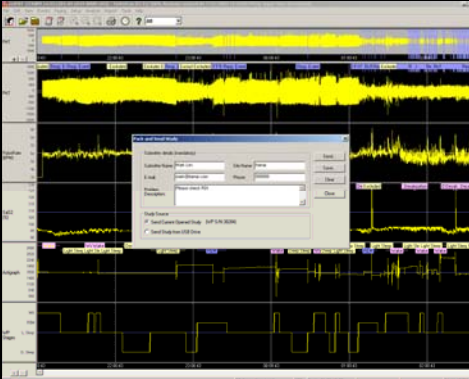
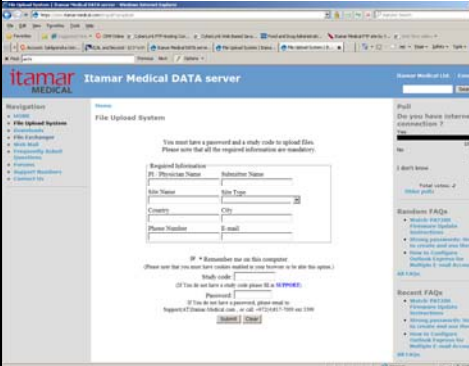
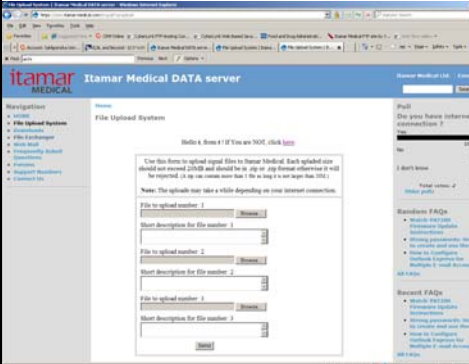
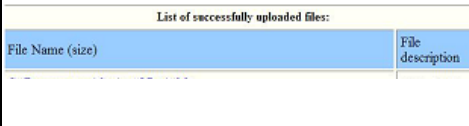
Press Alt +X (X is the character in the word that has underscore)

Special Keys:

F1	– Help
Ctrl+N	– New study
Ctrl+O	– Open study
Ctrl+F4	– Close study
Ctrl+L	– Load from flash and analyze
Ctrl+P	– Print
Ctrl+C	– Copy
Ctrl+F	– Active channel fit to window
Shift+F	– Fit to window all signals
I	– Zoom in
O	– Zoom out
Ctrl+Left arrow	– Previous Event
Ctrl+Right arrow	– Next Event
Shift+Left arrow	– Previous Same Type Event
Shift+Right arrow	– Next Same Type Event
Ctrl+Home	– First Event for channel
Ctrl+End	– Last Event for channel
Ctrl+R	– Sleep Report
Ctrl+I	– Sleep Indices
Alt+Add	– Increment active signal amplitude
Alt+Minus	– Decrement active signal amplitude
Alt+ Right arrow	– Zoom In to next timebase
Alt+ Left arrow	– Zoom out to next timebase
Home	– Go to First Page
End	– Go to Last Page
Page Down	– Go to Next Page
Page Up	– Go to Previous Page
Left arrow	– Scroll left
Right arrow	– Scroll right

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Appendix D: Manual Sleep data signal transfer

<p>Sending data for evaluation to Itamar</p>	<ul style="list-style-type: none">• Open in zzzPAT the study you want to send• Select Help → Prepare And Send Study to Itamar Medical...• Fill in the required information and select “Send current open study”• Select “Save” and save the study in your local drive (Preferable into disk on key or other removable drive)• Browse into URL: http://support.itamar-medical.com/upload• Fill in the required information<ul style="list-style-type: none">• PI / Physician Name• Submitter Name• Site Name• Site Type• Country• City• Phone Number• E-mail• Enter study code: <i>call Itamar for code</i>• Enter password: <i>call Itamar for password</i>• Press Submit• Browse and enter the file you have saved• Enter description for file• Press Send• At the end of the upload process make sure to get a message: “List of successfully upload files” and the list of files you uploaded	    <table><thead><tr><th>File Name (size)</th><th>File description</th></tr></thead><tbody><tr><td></td><td></td></tr></tbody></table>	File Name (size)	File description		
File Name (size)	File description					

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Appendix E: Index

A

Analyze>Reload study and analyze · 59
Archive · 84, 85, 86, 88, 89

B

Backup · 89, 94

C

Compact Flash
Defining drive · 16
Installation · 4
Set Flash Drive · 21

D

Database Tools · 85, 92, 93, 94, 100
Database upgrade · 16
Database Wizard · 15, 16, 37, 92, 93, 94, 95, 97, 100

E

Edit>Copy · 60
Event
Management · 60
Events
Deleting · 61
Events>Add Event · 60
Events>GoTo Event · 62
Events>Select Event · 62, 63
Export · 19, 30, 79, 84, 85, 86, 87, 88, 89, 94
Export a report · 63
Export From Database · 94

F

File>Close Study · 50
File>Exit · 50

File>Export Data · 79
File>Export Events · 79
File>Load Study and Analyze · 48
File>New Study Details · 38, 39, 48
File>Open Study · 49
File>Print · 78

H

Hardware Requirements · 3
Help
Prepare and Send Study to Itamar Medical · 80, 81

I

Import to Database · 87, 94

O

ODI · 65, 66, 71, 74, 107

P

pAHI · 65, 66, 71, 73
pRDI · 65, 71, 74, 107
pREM · 66, 107, 108
Printing · 78
Print a report · 63

R

Report · 63
Clinical Diagnosis · 63
Event Report · 71, 72, 73
Patient Follow-up Report · 74
Sleep Report · 65, 67
Restore · 89, 95

S

Setup>Directories · 21

Itamar Medical Ltd.

Setup>Set Flash Drive · 21
Setup>Settings · 21, 25
 Colors · 23
 Events · 26
 History · 27
 Medications · 28
 Montage · 22
 Report Appearance · 34
 Report Translation · 35
Status Bar · 55
Study
 Adding clinical information · 44
 Adding Demographic information · 43

T

Transferring a Study to Itamar Medical · 79

U

User
 Add User · 18
 Deactivate · 20
User Administration · 18, 20, 92, 100

V

View >All Night Channel Fit to Window · 58

View>Activate Channel Fit to Window · 58
View>All Night Window · 52, 59
View>Channels · 52, 54, 56
View>Fit To Window Mode · 58
View>Grid On/Off · 58
View>Relative Time · 58
View>Set y-Scale · 56
View>Study Details · 51
View>Time Base · 58
View>Zoom In · 59
View>Zoom Original · 59
View>Zoom Out · 59

W

Windows XP
 Permissions · 97
 Restrictions · 2

Z

zzzPAT
 Installation · 5
 Upgrading · 15
 Using · 37

Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APPLE INC.,)	
)	
Plaintiff,)	
)	C.A. No. 22-1377-MN-JLH
v.)	
)	JURY TRIAL DEMANDED
MASIMO CORPORATION and)	
SOUND UNITED, LLC,)	
)	
Defendants.)	
<hr/>		
MASIMO CORPORATION,)	
)	
Counter-Claimant,)	
)	
v.)	
)	
APPLE INC.,)	
)	
Counter-Defendant.)	
<hr/>		
APPLE INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 22-1378-MN-JLH
)	
MASIMO CORPORATION and)	JURY TRIAL DEMANDED
SOUND UNITED, LLC,)	
)	
Defendants.)	
<hr/>		
MASIMO CORPORATION and)	
CERCACOR LABORATORIES, INC.,)	
)	
Counter-Claimants,)	
)	
v.)	
)	
APPLE INC.,)	
)	
Counter-Defendant.)	

**AGREED PROTECTIVE ORDER
REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL**

Plaintiff and Counter-Defendant Apple Inc. (“Plaintiff”), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, “Masimo”) anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material (“Order” or “Protective Order”).

1. **PURPOSES AND LIMITATIONS**

(a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party’s attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

2. DEFINITIONS

(a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.

(b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.

(c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.

(d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

and 10,984,911 and any other patent asserted in these cases, as well as any related patents, patent applications, provisional patent applications, continuations, and/or divisionals.

(e) “Party” means any party to these cases, including all of its officers, directors, employees, consultants, vendors, retained experts, and outside counsel and their support staffs.

(f) “Producing Party” means any Party or non-party that discloses or produces any Discovery Material in these cases.

(g) “Protected Material” means any Discovery Material that is designated as “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL - OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE,” as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.

(h) “Receiving Party” means any Party who receives Discovery Material from a Producing Party.

(i) “Source Code” means computer code, scripts, assembly, binaries, object code, source code listings (e.g., file names and path structure), descriptions of source code (e.g., descriptions of declarations, functions, and parameters), object code listings and descriptions of object code, Hardware Description Language (HDL) or Register Transfer Level (RTL) files that describe the hardware design of any ASIC or other chip, and native Computer Aided Design (CAD) files that describe the hardware design of any component, the disclosure of which to another Party or non-party is likely to cause harm or competitive disadvantage to the Producing Party. To avoid any doubt, still images of CAD files are not Source Code and will not be subject to the

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as “CONFIDENTIAL” or “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” as provided for in this Order.

3. **COMPUTATION OF TIME**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **SCOPE**

(a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party’s own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party’s right to use any Protected Material with the consent of the Producing Party or by order of the Court.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. **ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) **Basic Principles.** All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.

(b) **Patent Prosecution Bar.** After the adoption of this provision by the parties, Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, “prosecution” as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancellation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party’s “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party’s Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party’s Protected Material for any purpose not permitted by Section 1.

(c) Secure Storage, No Export. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties’ Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties’ Outside Counsel

may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

(d) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.

(e) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE.”

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include “electronically stored information,” as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains “CONFIDENTIAL,” “CONFIDENTIAL - ATTORNEYS’ EYES ONLY,” or “CONFIDENTIAL - OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE,” material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of “This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative

Protective Order in this matter or pursuant to written stipulation of the parties.” Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent’s counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL” if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL” may be disclosed only to the following:

(i) The Receiving Party’s Outside Counsel, such counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;

(vi) The Court, jury, and court personnel;

(vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.

(ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(x) Any other person with the prior written consent of the Producing Party.

9. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – ATTORNEYS’ EYES ONLY”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” may be disclosed only to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

(c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as “CONFIDENTIAL - ATTORNEYS’ EYES ONLY.”

10. **DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE”**

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as

“CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

(b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.

(c) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL – OUTSIDE ATTORNEYS’ EYES ONLY - SOURCE CODE” shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:

(i) The Receiving Party’s Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel’s immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

11. **DISCLOSURE AND REVIEW OF SOURCE CODE**

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

(b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.

(c) Source Code that is designated "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:

(i) All Source Code shall be made available by the Producing Party to the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

(ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.

(iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.

(iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.

(v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

(viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.

(ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.

(x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).

(xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

(xii) Except as provided in this section, absent express written permission from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials

containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled “CONFIDENTIAL - ATTORNEYS’ EYES ONLY - SOURCE CODE” as provided for in this Order.

12. **NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as “Person”), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

- (i) the name of the Person;
- (ii) an up-to-date curriculum vitae of the Person;
- (iii) the present employer and title of the Person;
- (iv) an identification of all of the Person’s past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

(v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and

(vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

(b) Within ten (10) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, “good cause” shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the “Agreement to Be Bound by Protective Order” (Exhibit A hereto) and serve it on all Parties.

(e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. **CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

(b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.

(c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. SUBPOENAS OR COURT ORDERS

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY" or "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

(a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.

(b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. **INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(d) and (e), the inadvertent production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

(b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.

(c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material

is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” shall apply on a going forward basis and shall not disqualify anyone who reviewed “CONFIDENTIAL,” “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” materials while the materials were not marked “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” or “CONFIDENTIAL – ATTORNEYS’ EYES ONLY – SOURCE CODE” from engaging in the activities set forth in Section 6(b).

19. **INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. **FINAL DISPOSITION**

(a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, “Final Disposition” occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.

(b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

(a) Right to Further Relief. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) Termination of Matters and Retention of Jurisdiction. The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.

(d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.

(e) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

POTTER ANDERSON & CORROON LLP

PHILLIPS MCLAUGHLIN & HALL, P.A.

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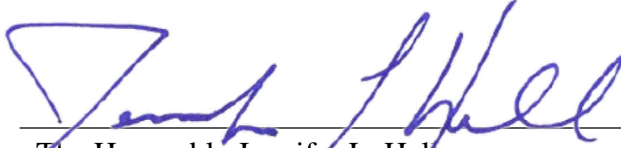
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Attorneys for Plaintiff Apple Inc.

Dated: June 14, 2023

IT IS SO ORDERED this 16th day of June, 2023.



The Honorable Jennifer L. Hall
United States District Court Magistrate Judge

EXHIBIT A

I, _____, acknowledge and declare that I have received a copy of the Protective Order (“Order”) in *Apple Inc. v. Masimo Corp. et al.*, United States District Court, District of Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH. Having read and understood the terms of the Order, I agree to be bound by the terms of the Order and consent to the jurisdiction of said Court for the purpose of any proceeding to enforce the terms of the Order.

Name of individual: _____

Present occupation/job description: _____

Name of Company or Firm: _____

Address: _____

Dated: _____

[Signature]

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